Training Manual

STAT PROFILE®

pHOx®

nova biomedical

Stat Profile pHOx Training Record

Instructor's Name: _____

Trainee's Name: _____

	Date Completed/Initials
Handling and Running Patient Samples	_____
Handling and Running Controls	_____
Replacing the Reagent Pack and Paper	_____
Identifying Flow Path and System Components	_____
Calibrating the Analyzer	_____
Daily Maintenance	_____
Troubleshooting	_____

QUICK REFERENCE

Key Facts (pHOx) QR-1
Maintenance Planner QR-2
Resolving Results Problems QR-3
Key Facts (BioProfile pHOx) QR-4

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Key Facts (pHOx and pHOx Basic)

NOTE: *The pHOx Basic Analyzer measures only pH, PCO_2, and PO_2.*

Sample Volume: 45 microliters whole blood (Micro sample)
70 microliters whole blood (Normal sample)

Slope Limits:

pH	9.1 - 11.6
PCO_2	7.9 - 12.6
PO_2	(-15.0) - (-1.6)
SO_2	6.9 - 18.2
Na^+	8.8 - 11.5
Hct	12.0 - 50.0

Measurement Range:

pH	6.50 - 8.00	pH units	H^+ 316.23 - 10.00 nmol/L		
PCO_2	3.0 - 200	mmHg	0.4 - 26.7	kPa	
PO_2	0 - 800	mmHg	0.0 - 106.7	kPa	
SO_2	0.0 - 100	%	0.0 - 1.0		
Hb	4.0 - 24.0	g/dL	40.0 - 240.0	g/L	2.5 - 14.9 mmol/L
Hct	12 - 70	%			

Dependency Rule and Information:

Hct	Requires Na+ calibrated for calibration/results.
PCO_2	Requires pH calibrated for results. (pH is checked on standards to assure bicarb is correct.)
SO_2	Requires Hct and PO_2 calibrated for results (uses calculated SO_2 if measured SO_2 is not available).
Hgb	Requires Hct and SO_2 for reporting. Priority: 1. If linked with the CO-Ox, then CO-Ox Hgb is reported. 2. If no CO-Ox or measured result, calculated result from Hct reading (Hct/3) is reported. 3. If no CO-Ox, no measured, and no Hct, analyzer reports Default Value (Hgb).
$P50$	Measured reported only with PO_2 between 30 and 75 mmHg. P50c is reported when PO_2 is outside above limits. Also $P50$ requires calibrated SO_2% and Hgb/Hct for reporting.
Qsp Qt	Requires 2 separate blood samples for determination: mixed venous and arterial.
RI	Utilizes input or default FIO_2% for calculation.
Calculated Results	Requires calibrated and proper results by measured tests used in calculation.
Suppression (Hgb)	Only Hgb can be suppressed. Your option is to turn Hgb from measured to calculated (one or the other will always appear). Option is done in the Setup Menu.

Maintenance Planner

NOTE: *For the BioProfile pHOx, SO_2 is not applicable.*

Weekly	Reposition Tubing in Pinch Valves
	Record Slopes

Monthly	Calibrate SO2

Quarterly	Clean SO2 Sensor and Cuvette
	Replace Pump Tubing
	Replace W-line
	Replace R-line

As Needed		
Deproteinize Probe/Sensor Module	Replace Probe	Replace Reagent Pack
Replace PO2 Cap	Condition pH Sensor	Replace Control Pack
Replace PCO2 Cap	Replace Sensors	Replace Printer Paper

Resolving Results Problems

Flow problems are often accompanied by sensor related problems. Do not change sensors or membranes until flow problems have been resolved first.

NOTE: *For the BioProfile pHOx, use protein solution instead of whole blood; blood gases are just gases; SO_2 is not applicable.*

Blood Gases	
PO2/PCO2	
Results High or Low	Verify controls are at room temperature
	Check for low slope
	Change membrane
	Change sensor
	Debubble sensor
	Condition sensor module w/whole blood
	Calibrate
	Check for air leak in system
	Clean probe and preheater
	Check waste line for restrictions

SO2	
Results High or Low	Recalibrate, clean cuvette and sensor, inspect or replace washer
pH	
Results High or Low	Verify controls are at room temperature
	Check for low sensor slope (<9.5)
	Condition w/pH Conditioning Solution
	Condition sensor module w/whole blood
	Verify reference solution delivery
	Change pH sensor
	Change reference electrode

Key Facts (BioProfile pHOx)

Sample Volume: 300 microliters sample size for full panel

Slope Limits:

pH	9.1 - 11.6
PCO_2	7.9 - 12.6
PO_2	(-15.0) - (-1.6)

Measurement Range:

pH	5.00 - 8.00	pH units			
PCO_2	3.0 - 200	mmHg	0.4 - 26.7	kPa	
PO_2	0 - 800	mmHg	0.0 - 106.7	kPa	
BarP	400.0 - 800.0	mmHg	53.3 - 106.7	kPa	15.7 - 31.5 inHg

Dependency Rule and Information:

PCO_2	Requires pH calibrated for results. (pH is checked on standards to assure bicarb is correct.)
Calculated Results	Requires calibrated and proper results by measured tests used in calculation.

NOTES:

Stat Profile® pHOx® Customer Training Programs

Stat Profile® and pHOx® are registered trademarks of Nova Biomedical.

Training on the Stat Profile pHOx Analyzer is intended to be carried out by a Nova training specialist utilizing this training guide, the reference manual shipped with the analyzer, training aids, and supplemental hands-on exercises as appropriate.

Training has been designed to be carried out in several stages corresponding to the operator's involvement level. When carried out at your location, the time you make available per training session will determine how much material can be covered.

Basic operator training requires approximately 1-2 hours, based on analyzer features and the participants' prior experience. Key or principal operator training requires an additional 2 hours of training. See the following page for topics generally covered.

For additional information on training programs and materials, contact the Nova customer training department at:

(800) 545-NOVA ext. 571

NOTES:

Learning Objectives

Basic Operator Training is designed to provide a new (first line) operator with skills to:

- Perform analyses of patient and QC samples
- Locate and use selected software screens and functions
- Identify major components
- Perform routine maintenance procedures
- Identify error conditions
- Carry out simple corrective procedures
- Use the reference manual or the Nova Hot Line as necessary

Key Operator Training adds those skills and information to:

- Perform all routine maintenance procedures
- Locate and utilize all necessary software screens and functions
- Identify performance trends and patterns
- Introduction to Nova support service
- Customize maintenance schedules
- Apply advanced troubleshooting techniques to resolve fluidic, calibration, and results-related problems
- Identify pre-analytical and other sources of sample handling error
- Use troubleshooting guides to resolve results-related problems
- Train additional operators in the workplace

Management Options will be discussed with the medical and/or technical director. They include the following:

- Adapting the analyzer to the facility's needs (setup options)
- Guidelines for analyzer performance verification
  (See *Getting Your Nova Analyzer On Line*, PN 17361.)
  - Linearity
  - Precision
  - Correlation
- QA Program options
- CLIA compliance

NOTES:

1 System Identification

1.1 System Overview

- The display is a backlit liquid crystal display (LCD) for menus and messages. Menus allow use of operating options and features.
- The keypad is the primary input device.
- The internal printer prints patient results, QC, setup information, error log, etc.
- The analytical compartment is where all calibration reagents enter and the sensor measurements take place.
- Reagents enter from the reagent pack. Waste materials (samples and reagents) are expelled into the reagent pack waste bottle.
- Sensors and air detectors are automatically calibrated periodically to insure accuracy.

NOTES:

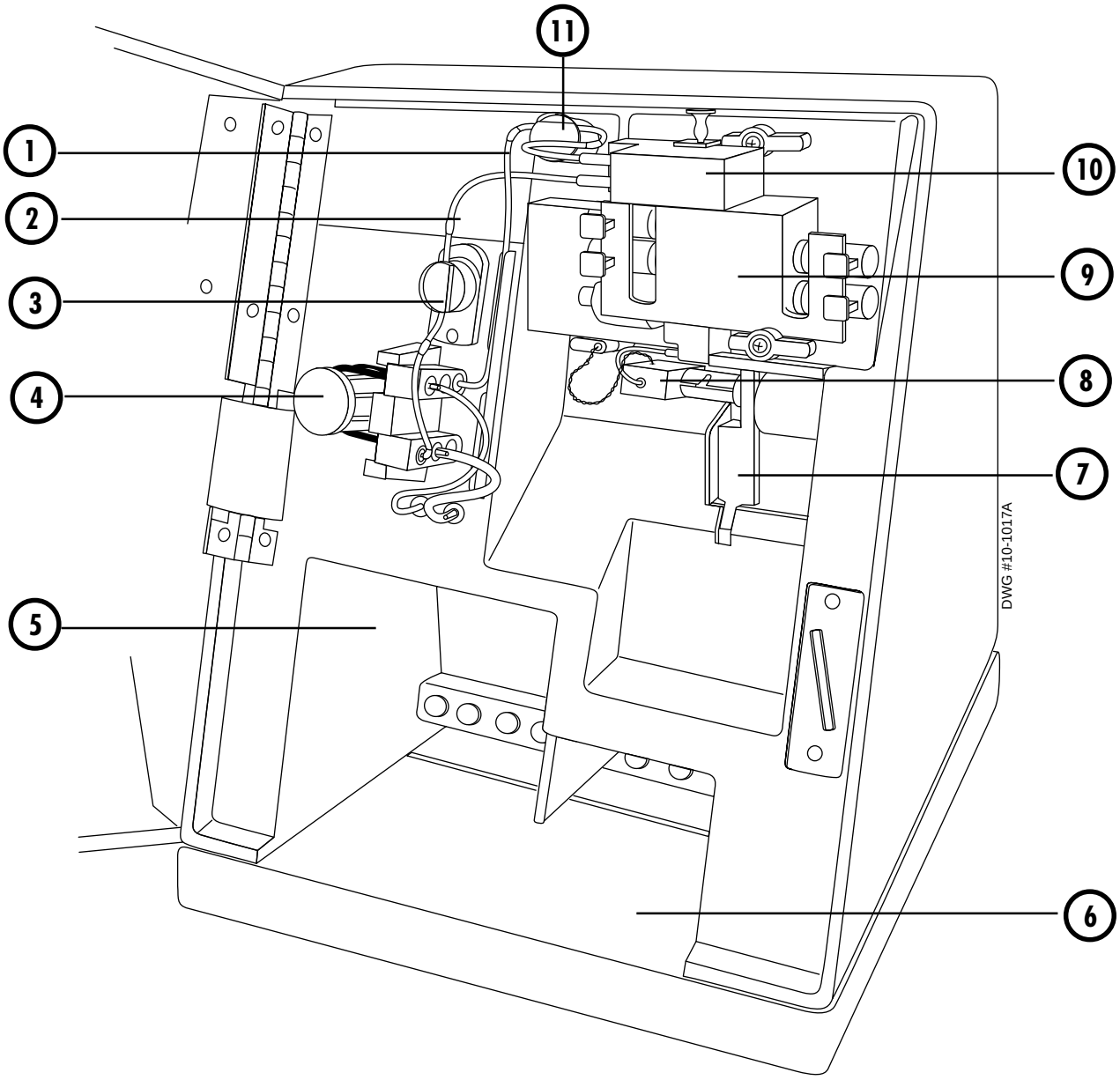


Figure 1.1 Analytical Compartment

1. Waste Line
2. Reference Line
3. Pinch Valve (Reference)
4. Pump and Pump Tubing
5. Reagent Pack Opening
6. Control Pack Opening
7. Sampler
8. Air Detector
9. Sensor Module with Sensors
10. Reference Electrode
11. Pinch Valve (Waste)

NOTES:

1.2 Flow Overview

1.2.1 Reagents

Instructor shows all these parts as they are described.

Reagents are drawn from the **reagent pack,** through the reagent harness, through the **rotary valve,** to the **fluid fountain** by way of the sample tubing, where they are aspirated by the **sample probe.**
The sample probe can aspirate different reagents depending upon the position of the rotary valve.
Aspirated fluids are drawn through the **probe**, the air detector, the **sensor module** with sensors, **reference electrode,** around the **pump** and out through the **waste line** to the **waste container** in the **reagent pack**.

1.3 Flow Components

1.3.1 Reagent Pack

The reagent pack contains 6 flexible bags in a cardboard carton. One of these is a waste bag to collect the used reagents, controls, and samples. The other 5 bags contain standard reagents: A, B, C, D, and R. Each bag includes a polyethylene fitment with a septa seal. The waste bag has a hydrophobic air vent.
Septa are arranged in a line along the rear of the pack. The septa are pierced during insertion of the pack. The lot number and expiration date are at the front of the pack.

Instructor points out that the reagent pack can be inserted and removed a few times.

The Reagent Management System (RMS) of the reagent pack automatically enters the calibration values, the lot number, the fluid volumes, and the expiration date to the analyzer's computer after insertion of the reagent pack.

NOTES:

1.3.2 Reagent Harness

The Reagent Harness transports reagents from the reagent pack to the rotary valve. It is replaced as part of annual maintenance by Nova Service.

1.3.3 Pinch Valves

There are 2 pinch valves: one is used to control the flow of the reference fluid and the other one is used to control the flow of fluids through the flow cell.

1.3.4 Peristaltic Pump

The pump is a 6-roller peristaltic pump driven by a stepper motor.

1.3.5 Sampler Assembly — Sample Probe

The sampler allows for the aspiration of the sample. The sampler has 2 sampling positions: horizontal for the aspiration of a sample from a capillary tube and inclined for the aspiration of the sample from a syringe. A capillary adapter automatically moves to the end of the probe when the Capillary Analyze key is pressed. No special adapters are required to aspirate a sample from a capillary tube. The capillary or syringe positions are selected by pressing the Black Capillary key or the White Syringe key.

NOTES:

1.3.6 Sensor Module

The sensor module includes the preheater and flow cell. The preheater preheats samples and controls to 37°C. In addition, it contains the hematocrit impedance sensor and 2 air detectors. The sensor module geometry is an interlaced configuration with the reference electrode at the top of the sensor module, 3 sensors on the left side, 2 sensors on the right side. In addition to the Hct sensor located in the preheater, there are 6 sensors: Reference Electrode, Na^+, PCO_2, SO_2 (optic), pH, and PO_2. A window in the door allows flow path visibility and is augmented by a backlight.

1.3.7 Sensors

The Sensors housed in the sensor module are the core of the Stat Profile pHOx Analyzer. The methodology used by each sensor are

Sensor	Methodology
Na^+	Sodium ion-selective electrode
pH	Hydrogen ion-selective glass electrode
PCO_2	Severinghaus-type electrode
PO_2	Polarographic Clark-type electrode
Hct	Impedance electrode
Hb	Impedance electrode/photometry
SO_2	Reflectance photometry (fiber optics)

The sensors clip into the sensor module, and an electrical contact is automatically made.

NOTES:

1.3.8 Reference Electrode

The Reference Electrode is mounted above the sensor module. It is a solid-state Ag/AgCl electrode and provides the reference voltage for comparison to sample voltages. The exit port of the flow path is located on this electrode.

1.3.9 Sensor Blanks (PN 22507)

Sensor Blanks (see Figure 1.2) are used in place of sensors that are not present on the analyzer or that are removed for certain maintenance and troubleshooting procedures. Periodically (as needed) remove blanks and clean the flow cell and tip of the blank with a cotton-tipped applicator that is moistened with bleach.

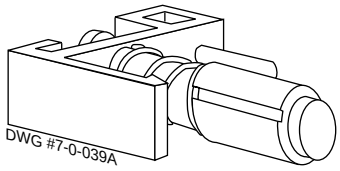


Figure 1.2 Sensor Blank

1.3.10 Interconnect Tubing (PN 07161)

Interconnect Tubing is installed between the reference electrode and the sensor module.
Required for the proper sealing of these components.

1.3.11 Barometric Pressure Module

The Barometric Pressure Module, located on a printed circuit board, continuously monitors the barometric pressure. This barometer can be calibrated against an external barometer, if desired, through the software.

NOTES:

1.3.12 Pump Tubing

The pump tubing has 2 manifolds (a top and bottom) and reference and waste tubing, labelled R and W. The top manifold can be identified by the half circle (right-sided). The R and W-pump tubing are connected to the corresponding labeled outlets below the pump.

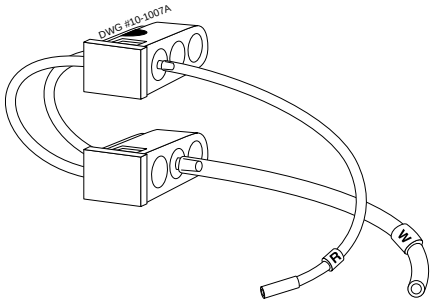


Figure 1.3 Pump Manifolds and Tubing

NOTES:

NOTES:

2 Running an Analysis

2.1 Is the Instrument Ready for Analysis?

2.1.1 Home Screen

Check the Home screen for Ready to analyze. The screen displays all analytes with the uncalibrated ones x'd out. Also, the next QC and Calibration times are displayed. A bar graph for the amount of reagents and controls shows the approximate percent remaining.

2.2 Patient Samples — Acceptable Samples/Sample Handling

For whole blood analysis only.

No serum or plasma unless operator has validated the system for that purpose.

No urine, CSF, cardioplegia solution, or other body fluids.

2.2.1 Acceptable Samples

The acceptable sample is heparinized whole blood.

Nova instruments are designed for clinical environments to analyze actual patient specimens, not modified blood samples. Specimens removed from the patient, anticoagulated appropriately, and promptly analyzed are the only type of sample where the measurement results will be reliable. Matrix effects/interferences can occur when patient specimens are removed from the body, modified and then measured on a Nova instrument. For example, matrix effects have been seen on Nova analyzers when attempting to analyze samples collected from cell savers used in various surgical procedures. Also, evaluation laboratories run specimens from patients with a wide variety of pathologies and from patients who are being treated with a broad spectrum of therapeutic and pharmacological agents. Despite extensive clinical trials, it is not possible to anticipate every possible combination of transfused blood products, crystalloids, and drugs (or their metabolites) that may be present in a blood sample. As a result, some users have found that their particular patient mix has necessitated making adjustments to maintenance. For example, a high number of cardiopulmonary bypass pump or ECMO (extracorporeal membrane oxygenation) samples result in a need for increased analyzer maintenance. If you are experiencing excessive downtime, you may need to modify your own maintenance schedules. Nova's Clinical Applications Group will assist you in tailoring a maintenance program to meet these needs.

NOTES:

This means no EDTA (purple tops), NaF (gray tops), or uncentrifuged red tops.

A general rule of thumb for blood gas and electrolyte analysis is to run the sample within 15 minutes of the time it was collected.

PO_2... may increase in a blood sample collected into a plastic syringe and stored on ice. The NCCLS document C32-P discusses these increases.

2.2.2 Acceptable Anticoagulants

Sodium and lithium heparin resulting in a final concentration of not more than 20 I.U. per mL in blood are the only acceptable anticoagulants.

2.2.3 Syringe Handling Tips

1. Remove air at time of collection.
2. Mix sample thoroughly by rolling between hands.
3. Run as soon as possible after collection. Do not ice plastic syringes.*
4. Check for clots by expelling a drop of blood onto a gauze pad.
5. For repeat samples, expel any air left in syringe.
6. Position sample so that probe tip stays deep in the syringe but not touching the syringe plunger.

* NCCLS. Nov., 1993. *Considerations in the simultaneous measurement of blood gases, electrolytes and related analytes in whole blood*., NCCLS document C32-P. Vol. 13, No. 17.

NOTES:

2.2.4 Capillary Handling Tips

- Collect in heparinized capillary tubes only.
- Place metal "flea" (stirring bar) in capillary prior to collecting sample.
- Sample must be collected without air spaces or gaps in capillary.
- Using magnet, mix well after collection.
- Cover tube ends with removable caps (not clay seal) for transportation to lab.
- See additional notes in **Chapter 1** of the **Reference Manual.**

Instructor demonstrates analysis.

2.2.5 Sample is Presented and Analysis Occurs

Press the White Button (Syringe) or the Black Button (Capillary) to run an analysis. The Aspirate screen displays. Wait until the sample probe is in position. Present the sample to the probe.

Samples can be presented in a syringe, opened vacuum tube, sample cup, or capillary.

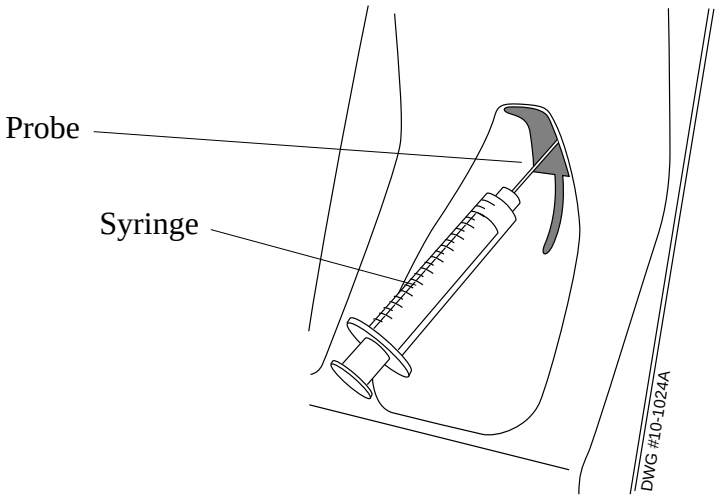


Figure 2.1 Syringe Sample Presentation

NOTES:

In STAT Mode Analysis, the Sample Information screen is not displayed. The ABG Results-Measured screen is displayed after aspiration is completed.

If the view results soft key is not selected the analysis will not go to completion. No results will be displayed or printed out.

***NOTE:** If you attach an external key board, alpha keys are available.*

After the sample is positioned, press Continue (soft Key). (If not pressed within 45 seconds, the analyzer returns to the Ready screen.) The pump turns, pulling the sample through the probe, air detector tubing, and sensor module. A pop-up screen appears. Remove the sample from the probe. Press Analyze. (If Analyze -soft key- is not pressed within 30 seconds, the probe will automatically move downward.) The probe moves downward.
The analyzer displays the Sample Information screen with a bar graph until completion.
Input sample information, then press View Results to see the completed results.

2.3 Sample Information

The Sample information screen is displayed after aspiration has been completed. This screen allows you to enter Accession number, Operator ID, Patient ID number, Combine with CO-Oximeter, combine with last sample for A/V & Shunt results, Patient temperature, and Sample Type. Use arrow keys to move to next option; Use the number keys or the Enter key to toggle or get pop-up selection.

2.4 Results Screen and Printout

The ABG Results -Measured screen is displayed and results fill in the table as they become available. The results on the screen can be printed by pressing Print (soft key). Press Next Page (soft key) to go to the next results screen, etc.

2.5 Running an Analysis Exercise

See **Running an Analysis Checklist** to perform the lab.

2.6 Standby Mode

See **Standby Mode Checklist** to perform the lab.

Running a Syringe Analysis Checklist

NOTES:

☐ Step 1 Check the instrument for readiness.

- Check the display for the Home (Ready) screen.

☐ Step 2 Present sample and begin analysis. (Procedure for syringes)

- Press the White Syringe Button.
- Probe positions for sample aspiration.
  Slide the syringe tip over the extended probe.

> ***CAUTION:*** *Do not allow the sample probe to touch the base of the syringe plunger or the bottom of the sample cup or tube.*

☐ Step 3 Analysis begins.

- Press Aspirate Normal (soft key) to start the sampling. (Or, press Aspirate Micro (soft key) for a smaller sample: 45µL instead of 70µL.)

> ***NOTE:*** *If one of these soft keys is not pressed within 5 minutes of the time the probe extends, the probe automatically starts to move down.*

- When the system signals by an audible alarm, withdraw the sample.
- Press Analyze. The probe moves down.

> ***NOTE:*** *If Analyze is not pressed within 30 seconds after the sample has been aspirated, the probe automatically starts to move down.*

- The analysis begins.
- The Sample information screen is displayed.

NOTES:

☐ **Step 4 Enter patient information.**

- The Sample information screen is displayed. (If in STAT Mode, this screen does not display. Go to next step.)
- Enter patient data.

> ***NOTE:*** *Press arrow keys to move through options. Press number keys or Enter key to toggle or get pop-up screen.*

If the View Results (soft key) is not pressed, the analysis will not go to completion and will not print out the results.

☐ **Step 5 Results are displayed and printed.**

- Press View Results (soft key) to view the results.
- Measured results are displayed on the ABG Results - Measured screen as they become available.
  Selected calculated results can be viewed by pressing Next Page (soft key) from the Results screen.
- To print the results, press Print (soft key).
- Results are transmitted to an optional external printer or computer, if enabled.
- After transmission and/or printout, all patient information becomes READ ONLY. They no longer can be changed or combined.
- Press Home (soft key) to return to the Home (Ready) screen.

Running a Capillary Analysis Checklist

NOTES:

Demo this before trainees attempt it. Skip this section if they do not run capillaries.

☐ Step 1 Check the instrument for readiness.

- Check the display for the Home (Ready) screen.

☐ Step 2 Prepare capillary. (See Section 2.2.4, Capillary Handling Tips)

- Mix sample again by drawing magnet back and forth along the length of the capillary.
- Keeping capillary level, remove cap (or caps) from the ends.
- Remove mixing flea by pulling it out one of the free ends with the magnet.

☐ Step 3 Present sample.

- Press the Black Capillary Button and wait for probe to position.
- Holding one gloved finger over the open end of the capillary, carefully slide the tip of the capillary into the adapter until it just touches the probe.
- The capillary should be in line with probe, not tilted horizontally.

> ***CAUTION: Do not*** *remove your finger from the open end of the capillary yet.*

☐ Step 4 Begin analysis.

- Press Aspirate Normal (soft key) to start the sampling. (Or, press Aspirate Micro (soft key) for a smaller sample: 45µL instead of 70µL.)

> ***NOTE:*** *If one of these soft keys is not pressed within 5 minutes of the time the probe extends, the probe automatically starts to move down.*

- As soon as the pump starts to turn, remove your finger from the open end of the capillary, allowing the sample to be drawn up.

NOTES:

- When the system signals by an audible alarm, remove the capillary from the probe and adapter.
- Press Analyze. The probe moves down.

  NOTE: *If Analyze is not pressed within 30 seconds after the sample has been aspirated, the probe automatically starts to move down.*

- The analysis begins.
- The Sample information screen is displayed.

☐ Step 5 Enter patient information.

- The Sample information screen is displayed. (If in STAT Mode, this screen does not display. Go to next step.)
- Enter patient data.

  NOTE: *Press arrow keys to move through options. Press number keys or Enter key to toggle or get pop-up screen.*

☐ Step 6 Results are displayed and printed.

If the View Results (soft key) is not pressed, the analysis will not go to completion and will not print out the results.

- Press View Results (soft key) to view the results.
- Measured results are displayed on the ABG Results - Measured screen as they become available.
  Selected calculated results can be viewed by pressing Next Page (soft key) from the Results screen.
- To print the results, press Print (soft key).
- Results are transmitted to an optional external printer or computer, if enabled.
- After transmission and/or printout, all patient information becomes READ ONLY. They no longer can be changed or combined.
- Press Home (soft key) to return to the Home (Ready) screen.

Running an AV Shunt Analysis Checklist

NOTES:

☐ Step 1 Check the instruments for readiness.

NOTE: *This checklist can only be performed if a Nova CO-Oximeter is in communication with the pHOx Analyzer, so that the results can be combined. This checklist may be removed if not needed.*

- Check the pHOx display for the Home (Ready) screen.
- Check the CO-Oximeter for readiness.
  (See the Nova CO-Oximeter Reference Manual.)

☐ Step 2 Present sample and begin analysis.

- Press the White Syringe Button.
  Probe positions for sample aspiration.
- Press the AV Shunt (soft key).
- Position the mixed venous sample over the extended probe.

CAUTION: *Do not allow the sample probe to touch the base of the syringe plunger or the bottom of the sample cup or tube.*

*You **must** press soft keys within 45 seconds or the cycle will abort automatically.*

☐ Step 3 Analysis begins.

- Press Aspirate (soft key).
- When the system signals by an audible alarm, withdraw the sample.
- Press Analyze (soft key). The probe moves down.
- The analysis begins.
- The Sample information screen is displayed; enter patient data.

NOTE: *Press arrow keys to move through options. Press number keys or Enter key to toggle or get pop-up screen.*

If Analyze is not pressed within 30 seconds after the sample has been aspirated, the probe automatically starts to move down.

Running an AV Shunt Analysis Checklist

NOTES:

☐ Step 4 Continue Analysis on CO-Oximeter.

- Analyze the mixed venous sample on the CO-Oximeter.

☐ Step 5 Run the Arterial Sample.

- When the message, Mixed Venous sample complete, position the arterial sample over the extended probe.
- Press Aspirate (soft key).
- After aspiration, remove arterial sample and press Analyze (soft key).

☐ Step 6 Continue Analysis on CO-Oximeter.

- Analyze the arterial sample on the CO-Oximeter.

☐ Step 7 Results are displayed and printed.

If the View Results (soft key) is not pressed, the analysis will not go to completion and will not print out the results.

- Press View Results (soft key) to view the results.
- Measured results are displayed on the ABG Results - Measured screen as they become available.
  Selected calculated results can be viewed by pressing Next Page (soft key) from the Results screen.
- To print the results, press Print (soft key).
- Results are transmitted to an optional external printer or computer, if enabled.
- After transmission and/or printout, all patient information becomes READ ONLY. They no longer can be changed or combined.
- Press Home (soft key) to return to the Home (Ready) screen.

Standby Mode Checklist

NOTES:

☐ Step 1 Start the procedure.

NOTE: *This option allows you to place the analyzer into a standby mode and allows you to reactivate the analyzer out of the mode at a programmed time and date. The standby mode will use less reagents and controls because the analyzer will not run its automatic calibration cycles. Calibration is lost except for SO_2 and Hb. Standby mode ends after the set time is elapsed, if you initiate a calibration, or if you turn Standby off.*

- From the Operational Menu, scroll down to the Standby Mode.
- Press ENTER (once if mode is OFF or twice if Mode is ON).

☐ Step 2 Set the date.

- Press ENTER (again) - the date becomes blank.
- Key in the date that you want the analyzer to come out of Standby Mode.
- Press ENTER to set the date. (DO NOT press OK.)

☐ Step 3 Set the time.

- Press any Arrow key to go to the time field.
- Press ENTER - the time becomes blank.
- Key in the time that you want the analyzer to come out of Standby Mode.
- Press ENTER to set the time. (DO NOT press OK.)

NOTES:

☐ **Step 4a Start the Standby Mode.**

- Now press OK (soft key) to initiate the Standby Mode.
- Another pop-up screen appears to verify that you want to go into Standby Mode. Press OK (soft key) again and the Standby Mode is officially ON.

☐ **Step 4b Cancel the Standby Mode.**

- Press Cancel (soft key) to cancel the Standby Mode.
- The date and time fields revert to the previous settings.
- The Standby Mode is now OFF.

NOTES:

3 Operational Status

3.1 Home Screen - Ready for Analysis

Indicates readiness of the analyzer.

- All analytes are shown. Uncalibrated analytes are x'd out and a — (a line through an analyte prefix) when the channel did not pass QC and QC lockout is enable.
- The Next Cal and if programmed the Next QC is displayed.
- Two fluid gauges display the approximate remaining solutions for the reagent cartridge and control cartridge.

3.2 Questionable Results

Results with a problem display a symbol in the Alert column. There are a number of symbols that can appear after the results. The symbols have the following meanings:

- ↑ **(single up arrow),** ↓ **(single down arrow)** - The result is higher or lower than the defined reference range for the parameter.
- ↑↑ **(double up arrow),** ↓↓ **(double down arrow)** - The result is higher or lower than the defined alert range for the parameter.
- ↑↑↑ **(triple up arrow),** ↓↓↓ **(triple down arrow)** - The result is out of the analyzer's operating range.
- **X (an X through an analyte prefix)** - The channel is uncalibrated.
- **? (question mark)** - Insufficient sample is detected during sample reading.
- *** (asterisk)** - The result is calculated using a default sodium concentration.
- **— (a line through an analyte prefix)** - The channel did not pass QC and QC lockout is enabled; or the results have been suppressed.

3.3 System Status Screen

This screen only appears if there are operational messages or status codes.

NOTES:

NOTES:

4 Calibrating the Analyzer

4.1 Full 2-Point Calibration - all except Hb and SO_2

- Uses internal calibrators (standards)
- Calculates slopes for sensors and air detectors
- Occurs at regular intervals or can be manually initiated by pressing Calibrate (soft key)
- Included as part of most maintenance routines
- Resets calibration timers
- Can generally be stopped by pressing Exit (soft key)
- Can be manually run by pressing the Calibration (soft key) from the Ready (or Not Ready) screen.
  1. The 2 pt. Calibration screen will display.
  2. Select option 1: pH, PCO_2, PO_2, Hct Calibration (ABG).
  3. Press Enter.

4.2 Calibration Timing

Auto calibration takes place at intervals of 2, 4, or 6 hours depending on analyzer activity. See **Chapter 3** of the **Reference Manual** for more details.

NOTES:

4.3 Other Types of Calibration

4.3.1 SO_2 and Hb Calibration

- Uses external calibrators (2 levels)
- Initiated by the operator monthly or as needed
- Access from Ready screen: Calibrate (soft key)
- Values for calibration (standards) are lot specific and must be verified or reentered at time of calibration.

See **Calibrating SO_2 and Hb Checklist**.

Instructor shows Calibration Configuration screen for calibration options. Access the Setup Menu (Password), select Operation Configuration Menu (press Enter). Select the Calibration Configuration option (press Enter). Discuss the options.

CLIA regs. require 30 minutes.

Mode A: One point fluid & Gas Cal done every 30-45 minutes.

Mode B: One point fluid & Gas Cal done with EACH analysis.

4.3.2 Single Point Calibration for Non-Gas Sensors

- Occurs with each gas Cal I (30-45 min. intervals) if Mode A is selected
- Occurs with each analysis if Mode B is selected
- Uses a calibration standard (either C or A) and increases time to appearance of results
- Checks for sensor drift
- Printing of drift is operator selected.

Calibrating SO_2 Checklist

NOTES:

☐ Step 1 Begin calibration.

- From the Home (Ready) screen, press Calibrate (soft key).
- Then select option 2: External two standard Hb, SO_2% Calibration then press ENTER.
- The External Standard Hb, SO_2% Calibration screen appears.

☐ Step 2 Verify calibrator (standard) values.

- Consult insert sheet for this lot and compare to values on the screen.
- Key in the assay value for Std. #1, if necessary.

☐ Step 3 Prepare calibrator #1.

- Mix gently by inversion.
- Open the ampule carefully to avoid injury (glass edges).
- Position Calibrator #1 so that the extended probe tip is well covered by the solution.
- Press Continue (soft key).
- When system signals by audible alarm, remove the ampule,
- Press Analyze (soft key).

☐ Step 4 Prepare calibrator #2.

- Repeat procedure for calibrator #2.
- Enter/verify assay value for Std. #2. (Press ENTER after entering the assay value.)
- Mix gently by inversion.
- Open the ampule carefully to avoid injury (glass edges).
- Position Calibrator #2 so that the extended probe tip is well covered by the solution.
- Press Continue (soft key).
- When system signals by audible alarm, remove the ampule,
- Press Analyze (soft key).

NOTES:

NOTES:

5 Using and Handling Controls

5.1 Controls

CAUTION: *Performance of the analyzer may be affected by the use of controls other than Nova controls and will void warranty on components that come into contact with them.*

The Stat Profile pHOx Analyzer has on board QC and on board controls. Controls can be analyzed either with the internal control pack or with external Nova control ampules.

5.1.1 Stat Profile pHOx Controls

- Monitor performance of all blood gases and electrolytes
- Contain no preservatives, dyes, or surfactants that can damage sensors or other flow components
- Formulated at 3 clinically significant levels:
  - L1 Acidosis, with low pH, high PCO_2, low PO_2, low SO_2, low normal Hct and low normal Hb values
  - L2 Normal, with normal pH, PCO_2 and PO_2 values
  - L3 Alkalosis, with high pH, low PCO_2, high PO_2 high SO_2, and normal high Hct/Hb values
- Internal in a self-containing control pack (Auto- Cartridge QC) or external in individual ampules

The Auto- Cartridge QC has a use-life of 35 days.

5.2 Handling Controls

5.2.1 Storage Temperature

Store at 25°C (77°F). Warmer or colder controls affect gases and pH. Hold vial between thumb and fingertip when shaking to avoid changing temperature. For every 1° C ***above*** 25°C, PO_2 recovery drops 1%. The opposite effect is seen at temperatures ***below*** 25°C.

CAUTION: *Do not refrigerate. Avoid storing controls on a window sill or near a heating or air-conditioned duct.*

NOTES:

5.2.2 Stability of Opened Ampules

Shake and analyze within 30 seconds of opening. Contamination with room air will begin to affect PO_2, PCO_2, and pH results after that time. Room air has a PO_2 of about 150 mmHg and a PCO_2 of ~0 mmHg. Exposure of controls to room air causes: PO_2 and pH to increase, PCO_2 to decrease.

5.2.3 Altitude and Barometric Pressure Effects

Aqueous controls are assayed at sea level. Changes in altitude will affect gas recovery. For every 1000 ft above sea level, PO_2 recovery drops by approximately 0.5%. An incorrect barometric pressure will also affect gas recovery. System barometric pressure is displayed on the printout, barometric pressure, or Status screen. If significantly different from a known, accurate measurement, enter an offset by selecting Setup, enter password, select Operations Configuration, press Enter, select System Configuration Menu (use arrow keys to go to corrected Barometric Pressure), enter mmHg, Press Home to exit to Home (Ready) screen.

5.3 When to Use

As of the date of publication of this guide, a minimum of one blood gas control must be analyzed every 8 hour shift of lab operation. Also, after maintenance or troubleshooting or as required by the laboratory's quality control program. All levels must be analyzed within a 24 hour period.

5.4 Using the Stat Profile pHOx's On-Board QC Features

The analyzer's QC features allow you to:

- Set ranges and units for acceptable results.
- Store statistics.
- Program for internal or external control source.
- Display or print QC statistics in the form of reports.
- Remind or require operators to run QC at specific intervals.
- Analyze other forms of QC such as proficiency surveys or linearity standards without "offsets".

NOTES:

These features must be enabled or setup before they can be used. See **Quality Control Setup** in the analyzer's reference manual for details. If you will be using them, the installer will have done at least a partial setup so that you can learn how they work.

5.4.1 The QC Soft key

This key has more than one function:

- To run a QC analysis either internal or external
- To view or to print QC data
- To set up QC levels
- To turn automatic QC analysis on or off

5.4.2 Automatic QC Analysis (Internal)

To use the Automatic QC Analysis feature properly, the QC analysis times need to be programmed under the Daily Analysis Times screen during the QC Setup and the Automatic QC Analysis needs to be turned on. QC is automatically performed at these programed times with the controls from the Auto-Cartridge QC.

NOTE: *Internal QC can also be run manually: see the checklist.*

5.4.3 Manual QC Analysis (External)

To use the Manual QC Analysis feature properly, the QC analysis times need to be programmed under the Daily Analysis Times screen during the QC Setup and the Automatic QC Analysis needs to be turned on. When QC analysis is needed, a Pop up screen will appear prompting you to run the required QC. Press OK (soft key). Then go to the Analyze QC screen and select the appropriate QC.

GO TO CHECKLIST.

Analyzing Controls Checklist

NOTES:

☐ Step 1 Preparing for Analysis

- Hold QC ampule between thumb and forefinger and agitate vigorously for several seconds.

NOTE: *Do not warm ampule in hands.*

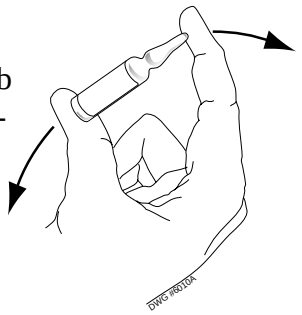


Figure 5.1 Agitating the Ampule

☐ Step 2 Initiating the QC Analysis

- Press QC (soft key) on the Home screen.
- With Analyze QC Highlighted, press ENTER.
- Select the QC to be analyzed, i.e., QC Level #1 External.
- Change if necessary by pressing Previous Control (soft key) or Next Control (soft key).
- Press the White Button (Syringe) or Analyze (soft key).

☐ Step 3 Completing the Cycle

- Once probe has extended, open the ampule while protecting yourself from the sharp glass edges.
- Fully immerse the probe into the fluid of the ampule. Do not allow the probe to touch the bottom of the ampule.
- Press Continue (soft key).
- When the system signals by an audible alarm, remove the ampule and press Analyze (soft key). The probe moves downward.
- Discard the ampule.

NOTE: *Failure to press Continue (soft key) within 45 seconds will cause the system to* ***time-out*** *canceling the cycle and returning you to the Quality Control screen.*

NOTES:

☐ Step 4 Accepting or Rejecting Results

When results are ready, they appear on the screen along with an indication of whether they have **passed** or **failed** the QC range check. If one or more tests are out of range, the QC Results screen flashes Exceed Limits.

- To save all data, press QC (soft key).
- To reject the data, press Delete (soft key). Then press Continue to discard all the data.
- All data is either accepted or rejected.

☐ Step 5 Repeat for next level

Analyzing Internal Controls Checklist

NOTES:

☐ Step 1 Preparing for Analysis

- From the Ready screen, press QC (soft key) on the Home screen.

☐ Step 2 Initiating the QC Analysis

- With Analyze QC Highlighted, press ENTER.
- Select the QC to be analyzed, i.e., QC Select Internal L1.
- Change if necessary by pressing Previous Control (soft key) or Next Control (soft key).
- Press Analyze (soft key).

☐ Step 3 Accepting or Rejecting Results

When results are ready, they appear on the screen along with an indication of whether they have **passed** or **failed** the QC range check. If one or more tests are out of range, the QC Results screen flashes Exceed Limits.

- To save all data, press QC (soft key).
- To reject the data, press Delete (soft key). A pop-up screen appears: enter your password. Then press Continue to discard all the data.
- All data is either accepted or rejected.

☐ Step 4 Repeat for next level

NOTES:

5.5 QC Data

To view QC data, select View or Print QC Data on the Quality Control (QC) screen then press Enter. The QC Data screen for the selected level is displayed. From this screen, you can view today's data, daily statistics, monthly statistics, cumulative, or Levey-Jennings.

5.5.1 View Today's Data

From the QC Data screen, select View Today's Data then press Enter. The QC Results screen is displayed. To view the next result, press Next Page (soft key). For options, press Options (soft key). A pop-up window appears. One option is for deleting this result. You can also print or view other statistics.

5.5.2 View Daily Statistics

From the QC Data screen, select View Daily Statistics then press Enter. This screen is the QC Daily Statistics for the selected level. From this screen, you can view the next level, and/or print the statistics.

NOTES:

5.5.3 View Monthly Statistics

The Monthly Statistics is a record of all QC accepted for the past month. Print this record for your files at the end of each calendar month.

1. From the Quality Control screen, select View or Print QC Data.
2. From the QC Data screen select **View monthly statistics**.
3. Press Print (soft key).

=======Stat profile QC Statistics======

Date 6-23-98 Time 10:54
Analyzer ID 0 Operator ID 1
Lot#1234567890 Exp 7-31-98

DAILY (n=6)

Test	Mean	±Range	SD	CV
pH	7.595	0.050	2.3	2.3
pCO_2	23.0	10.0	2.3	2.3
pO_2	155	12.0	1.0	1.0
SO_2	....	....	....	....
Hb	7.5	10.0	3.5	3.5
Hct	18	10.0	2.3	2.3

MONTHLY (n=97 during 30 days)

Test	Mean	±Range	SD	CV
pH	7.595	0.050	2.3	2.3
pCO_2	23.0	10.0	2.3	2.3
pO_2	155	12.0	1.0	1.0
SO_2	....	....	....	....
Hb	7.5	10.0	3.5	3.5
Hct	18	10.0	2.3	2.3

QC CUMULATIVE (n=1,498 during163 days)

Test	Mean	±Range	SD	CV
pH	7.595	0.050	2.3	2.3
pCO_2	23.0	10.0	2.3	2.3
pO_2	155	12.0	1.0	1.0
SO_2	....	....	....	....
Hb	7.5	10.0	3.5	3.5
Hct	18	10.0	2.3	2.3

Figure 5.2 QC Statistics Printout

NOTES:

5.5.4 Printing Levey-Jennings Charts

The Levey-Jennings data graph is displayed on screen. When printing, each graph will be rotated 90° with the date appearing on the long axis of the chart.

1. From the Quality Control screen, select View or Print QC Data.
2. From the QC Data screen, select **View Levey-Jennings**.
3. Highlight the analyte using the arrow key.
4. Press enter to view data on the screen.
5. Press Print (soft key).

```
=======Stat profile QC Statistics======
        LEVEY-JENNINGS CHARTS
Analyzer ID 0                 Operator ID  ...
Lot # 1234567890        Exp Date 07-31-98
Date      Lower Limit             Upper Limit
-----------------------------------------------------
                7.585   7.600             7.635
-----------------------------------------------------
11-23                  *
11-24                  *
11-25                   *
11-26                    *
11-27                       *
11-28                           *
11-29                      *
11-30                       *
12-01                       *
12-02                       *
```

Figure 5.3 Levey-Jennings Graphs Printout

NOTES:

NOTES:

6 Replacing Reagents and Paper

6.1 When to Replace

Replace the fluid pack and/or the control pack when it has reached its expiration date or when the graphic appears empty on the Home screen. Also, replace the capillary adapter found in the reagent pack.

6.2 How to Replace

To install a new reagent pack and/or control pack, you will be using one of the automated Operational Menu procedures: Change Reagent Pack or Change Control Pack. These procedures come up as screens with the steps necessary to carry out the changing of the pack. Because the reminders are brief, you should refer to the complete illustrated procedures located in the maintenance section of the analyzer's reference manual if you need additional details. To stop automated maintenance procedures, press Cancel (soft key).

The on-board Reagent Cartridge has a use-life of 45 days.

The on-board QC Cartridge has a use-life of 35 days.

6.3 Replacing the Reagent Pack

See **Replacing the Reagent Pack Checklist** to perform the lab.

6.4 Replacing the Control Pack

See **Replacing the Control Pack Checklist** to perform the lab.

6.5 Replacing the Printer Paper

See **Replacing the Printer Paper Checklist.**

Replacing the Reagent Pack/Capillary Adapter Checklist

NOTES:

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, septum assembly, probe, flow cell, etc.) with care. Gloves and protective clothing are recommended. Dispose of the reagent waste bottle according to your laboratory's biohazardous waste policies.

☐ Step 1 Replace the capillary adapter.

- From the Home (Ready) screen, press Menu.
- Select Change Pack.
- Press Enter. A pop-up screen appears.

Change Reagent Pack
Change Control Pack
Exit

- Highlight Reagent Pack.
- Press Enter.
- Press Move Probe (soft key).
- Open the door.
- Remove the capillary adapter from the front of the probe by pulling it off.
- Replace the adapter with a new one found in the reagent pack. As you put on the adapter, make sure the probe goes into the center hole of the adapter.
- Press Move Probe (soft key) when finished.
- Press Cancel then press Cancel again to return to the Home screen.

☐ Step 2 Remove old cartridge.

- Open the door.
- Remove the old cartridge - lift the cartridge up slightly to clear the lip.
- Mix the new cartridge by gently inverting for several seconds. DO NOT SHAKE THE PACK.
- Slide in the new cartridge.
- Close the door.

Replacing the Reagent Pack/Capillary Adapter Checklist

NOTES:

☐ Step 3 Prime the analyzer.

- Press Prime (soft key): this primes and validates the cartridge.

☐ Step 4 Calibrate the analyzer.

- After priming, a pop-up screen appears with a question, "Do you want to recalibrate? Yes or No." Press Yes (soft key).
- Calibration takes place.

☐ Step 5 Validate performance with QC.

- Run QC.
- Document the results.

Replacing the Control Pack Checklist

NOTES:

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, septum assembly, probe, flow cell, etc.) with care. Gloves and protective clothing are recommended. Dispose of the reagent waste bottle according to your laboratory's biohazardous waste policies.

☐ Step 1 Initiate the procedure

- From the Home (Ready) screen, press Menu.
- Select Change Pack.
- Press enter. A pop-up screen appears.

Change Reagent Pack Change Control Pack Exit

- Highlight Control Pack by using the down arrow key.
- Press Enter.

☐ Step 2 Follow the screen directions.

- Open the cover.
- Remove the old cartridge - lift the cartridge up slightly to clear the lip.
- Mix the new cartridge by gently inverting for several seconds. DO NOT SHAKE THE PACK.
- Slide in the new cartridge.
- Close the door.

☐ Step 3 Prime the analyzer.

- Press Prime (soft key).

☐ Step 4 Calibrate the analyzer.

- After priming, a pop-up screen appears with a question, "Do you want to recalibrate? Yes or No." Press Yes (soft key).
- Calibration takes place.

☐ Step 5 Validate performance with QC.

- Run QC.
- Document the results.

Replacement of the Printer Paper Checklist

NOTES:

☐ Step 1 Open the printer cover.

☐ Step 2 Lift print head.

- Open the printer platen.
- Gently pull the lever near the paper advance knob forward.
- Remove the depleted roll of paper.

☐ Step 3 Remove paper holder from the old roll of paper.

☐ Step 4 Install new roll of paper.

- Insert the paper holder into a new roll of paper. The loose end of the paper should feed from the bottom of the roll.
- Install the paper holder with paper into the support collars.
- Push the paper through the back of the roller.

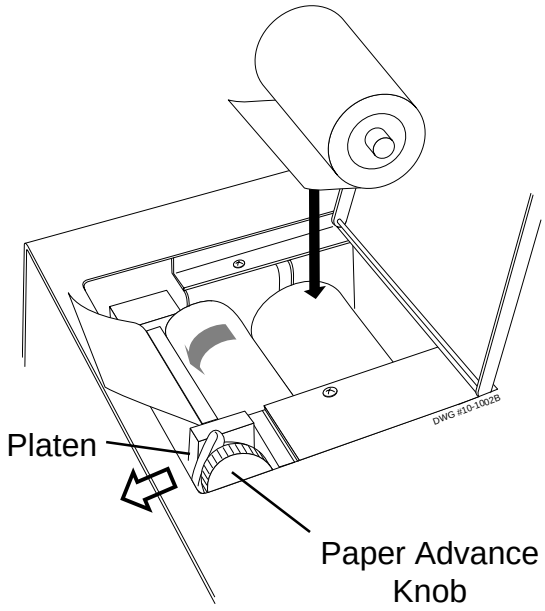


Figure 6.1 Paper Installation

☐ Step 5 Reposition print head.

- Center the paper and close the printer platen by moving the lever back to the original position.
- Advance the paper by using the paper advance knob.
- Feed the paper through the cover. Then close the cover.

NOTES:

☐ Step 6 Test printer (Optional).

- From the Home screen, press Menu (soft key); press Service (soft key); use the down arrow key to select Printer Menu: press ENTER; use the down arrow key to select Character Set Test; finally press ENTER to obtain a character printout to verify proper operation (see Figure 6.2).
- After the self test is completed, a pop-up screen appears. Press OK.
- Press Home (soft key) to return to the Home screen

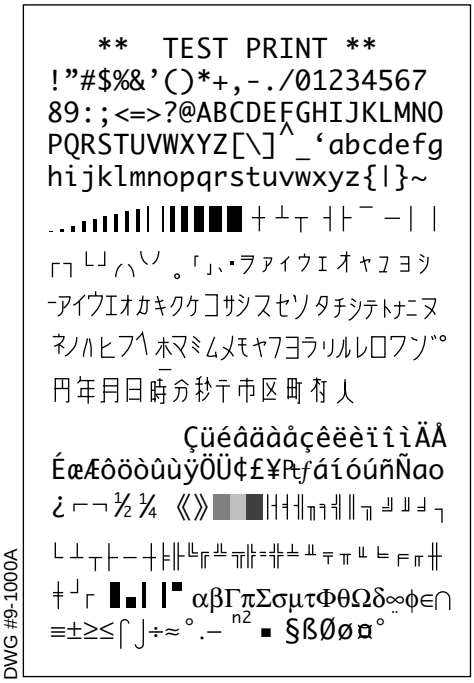


Figure 6.2 Sample Test Printout

NOTES:

7 Troubleshooting

Instructor: Show these screens as they are discussed.

7.1 Sensor Screens

For a full description of these screens, turn to **Chapter 6** of the **Reference Manual.**

From the Home screen, press Menu (soft key). Then press Service (soft key). Using the down arrow key, select Sensor Subsystem. Then press ENTER.

Calibration and analysis data for each sensor, the SO_2 LEDs, and the air detectors are contained on the following screens.

7.2 System Test

For a full description of this screen, turn to **Chapter 6** of the **Reference Manual.**

From the Home screen, press Menu (soft key). Then press Service (soft key). Using the down arrow key, select System Test then press ENTER.

The System Test screen displays millivolt readings for all sensors. From this screen, you can manipulate the pHOx Plus to perform many actions, i.e., priming. It also allows you to check the sampler, rotary valve, pump, waste valve, reference valve, ADTs, and SO_2 LEDs.

Turn to Chapter 6 of the Reference Manual for procedures on how to perform these tests.

The operator flow test is performed from the System Test screen by pressing Operator Flow Test (soft key). The pump turns on, the probe moves to the syringe position, and the waste valve opens. This allows the user to present a cup of water to the probe and observe the flow of water.

NOTES:

7.3 Error Log

From the Home screen, press Menu (soft key). Then press Service (soft key). Using the down arrow key, select Error Log and press ENTER.

This screen shows all errors displayed in chronological order followed by a short explanatory message - holds 96 errors.

For more detailed information, refer to the **Reference Manual (Chapter 5, Troubleshooting).**

An index lists all the status messages by code with a symptom and corrective action.

7.4 Flow Related Problems

The cause of flow problems are clots, hidden blockages, leaks, and pumping problems.

The errors show up as flow status codes. Resolve by referring to solutions described in the **Reference Manual, Troubleshooting** chapter, for that status code.

NOTE: *Always fix flow problems first.*

Flow problems are often accompanied by sensor related problems. Do not change sensors or membranes until flow problems have been resolved. Once flow problems are resolved, sensor problems often disappear.

Diagnose with flow tests: Water Test, Pump Test, and Reference Solution Test.

Water Test — Checks to verify that water can be pulled through the system from the probe. If water cannot be aspirated through the probe, a clog, leak, or a mechanical pump problem exists in the system.

Pump Test — Checks to verify that the pump and waste valve are functioning properly. Also verifies if the W-line from the reference electrode to the waste bottle is free of blockages.

Reference Solution Test — Verifies reference solution is getting to the reference electrode.

NOTES:

7.5 Sensor Problems

Problems may be uncalibrated, overload, instability, slope, drift, out of range, and dependency status codes.
Resolve by referring to solutions described in the **Chapter 5, Troubleshooting,** in the **Reference Manual** for that status code.

7.6 Results Related Problems

Problems may occur because sample results are either too high or too low. Can be combination of two or more results problems.
See **Resolving Results Problems** in the **Quick Reference** section.
Resolve by referring to solutions described in the **Chapter 5, Troubleshooting,** in the **Reference Manual** for that error code.

7.7 Miscellaneous Problems - Operational

Problems may be related to lab temperature, incorrect barometric pressure, open door, or reagent pack problems.
Resolve problems by lowering/raising temperature, correcting barometric pressure in the analyzer, closing door, and reinstalling/installing a new reagent pack.

7.8 Call Nova

For problems involving hardware, electronics, printer, or software error messages.
Problems that cannot be resolved by you or at your site.
Resolve problems by calling Nova Technical Services at 1-800-545-NOVA. Have the serial number and the closest phone extension to the instrument ready.

NOTES:

NOTES:

8 Flow Test and Flushing

8.1 Manual Flow Test Lab

WARNING: Use appropriate protective face shield, gloves, etc., when attempting to flush, clean or handle any components of the analyzer which come in contact with blood specimens.

The Stat Profile pHOx flow tests are used to troubleshoot fluidic problems that might give the following status codes:

- 71 Flow - No Std A
- 72 Flow - No Std B
- 73 Flow - No Std C
- 74 Flow - No Std D
- 75 Flow - Flow long/short
- 76 Flow - No sample
- 77 Flow - No air

The fluid system can be isolated into 3 large sections:

- Fluid Pack to fluid fountain
- Sampler/sensor module
- W/R-lines to waste tubing

Performing the flow test limits the search to one of the fluid sections.

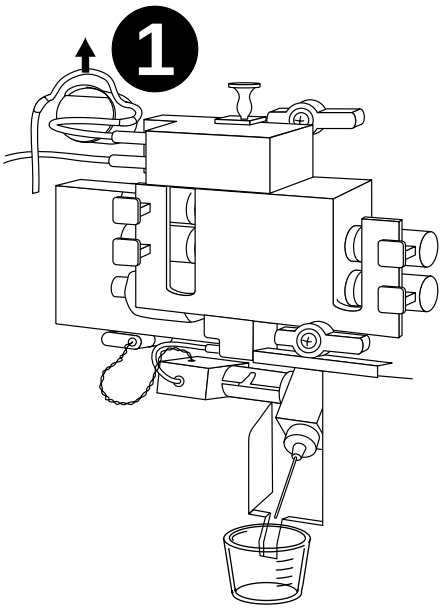
What you will need to do this test:

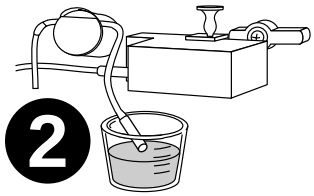
1. A sample cup, 25 mL medicine cup, or 25 mL beaker
2. Deionized water
3. Syringe with blunt needle and silicone tubing (probe cleaning kit or equivalent)
4. Lint-free tissue or gauze

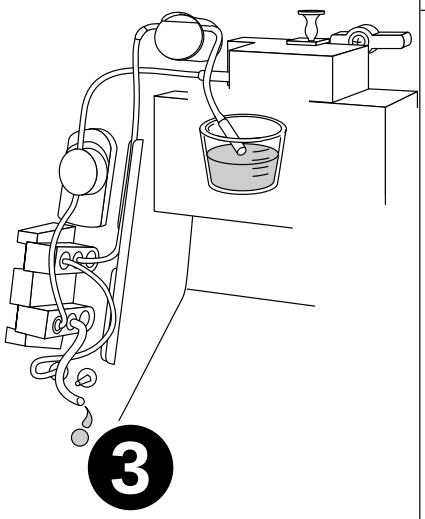
NOTES:

Operator Flow Test

From Ready→Service→System Test→Customer Flow Test







1 - Lift the tubing out of the Waste solenoid.
- If tubing remains pinched, roll it between fingers to loosen.
- Place the sample probe in a cup of water.

Is fluid flow noticed in the waste line tubing?

A. IF YES, call your Nova Service Representative.
B. IF NO, go to Step 2.

2 - Disconnect the Waste (W) from the Reference Electrode.
- Place this end of the W tubing into a cup of water.

Is fluid flow seen in the Waste line tubing?

A. IF YES, press "PUMP" to turn off the pump motor. Go to the next page, "Sensor Module Back Flush" procedure.
B. IF NO, go to Step 3.

3 - Disconnect the Waste line tubing from the front panel port.
- Place this end of the tubing over a gauze to prevent spilling.
- Aspirate water from the same location as in Step 2 above.

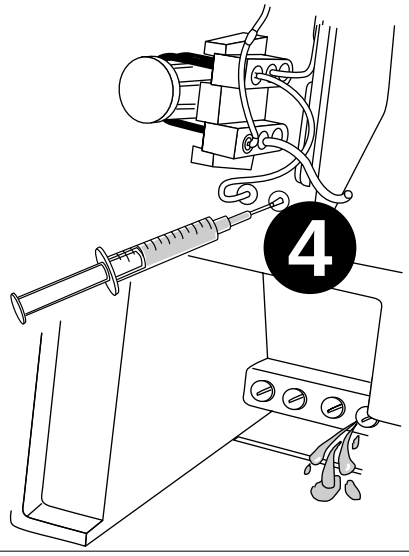
Is fluid seen exiting the Waste tubing end you just disconnected?

A. IF YES, go to Step 4.
B. IF NO, Replace the W/R Tubing Harness (P/N 23023)

4 - Press the "PUMP" key to stop the Pump Motor
- Remove the Reagents Cartridge from the unit.
- Install the flush adapter.
- Place the flush adapter tubes into an empty beaker.
- Inject water to the front panel Waste port.
- Water should flow through the adapter waste tube. (Adapter waste line is last to the right)

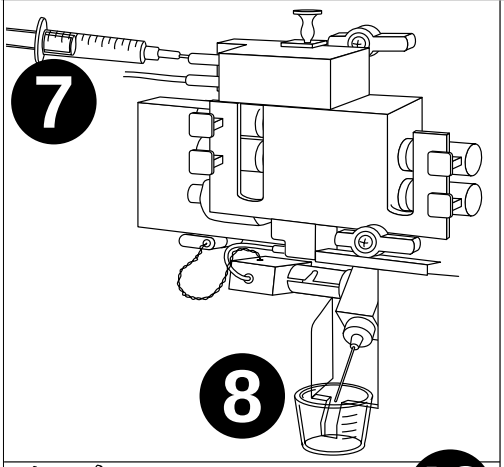
* Loss of Reference flow will change the flow rate. Reference solution will flow at a rate of 1 -2 drops/second during a pumping cycle.

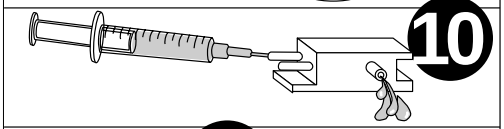
** If this tubing cannot be flushed call your Nova Service Representative. If tubing flushes easily, change the Reagents Cartridge. In a small number of cases the original problem may have been poor alignment of the Reagents Cartridge.

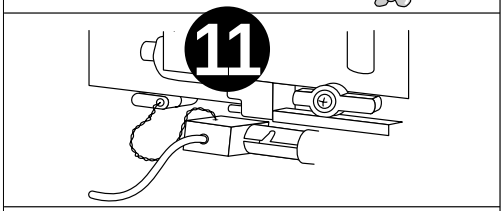


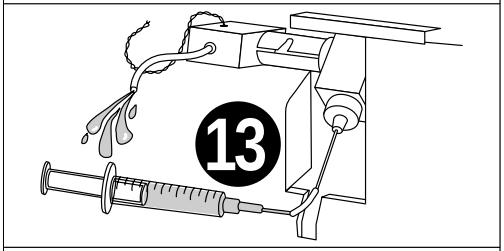
NOTES:

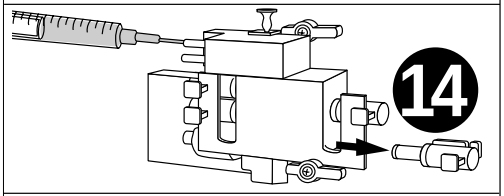
Sensor Module Back Flush Procedure

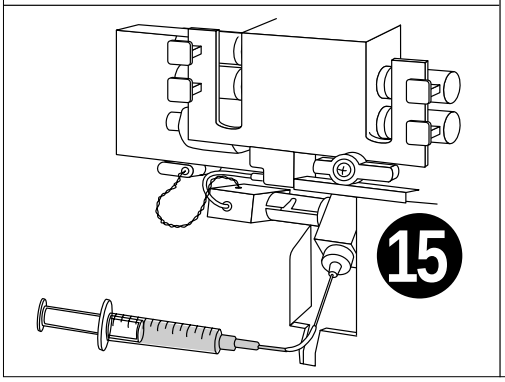












(5) If you are starting from the Operator Flow Test
-Turn the Pump OFF by pressing the "PUMP" key.

(6) If you are starting from the Ready Screen
- Press Service, System Test and select the Operator Flow Test.
- Turn the pump OFF as in Step 5.

7 Connect a syringe filled with water to the Reference electrode waste port.

8 Back flush the flow path by injecting the water.
Caution: Place a gauze or towel at the sample probe tip to receive the obstruction or water.

(9) If the water easily flushes through the sensor module, you may have an air leak into the flowpath. This will be from an interconnect tubing, failed membrane, or poorly seated electrode. Go to Step 15.

10 If water does NOT exit the sample probe.
- Lift the Reference electrode off the sensor module.
- Flush the Reference electrode.
If it flows freely, confirm that the interconnect tubing is properly positioned and reinstall the Reference Electrode.

11 Disconnect the Air Detector from the bottom of Sensor Module.

(12) Inject water into the W port of the Reference Electrode.
Does water flow through the sensor module?
IF YES, go to Step 13.
IF NO, go to Step 14.

13 - Connect the syringe to the Sample Probe tip.
- Inject water through the Probe
Water should exit the Air Detector (ADT) tubing.
IF NO flow is noted, flush the ADT and probe separately.
IF the water flows easily, the seal between the ADT and probe may be leaking. Replace the Air Detector.

14 (NO from Step 12) The obstruction lies in the flowcell. While continuing to inject, remove one electrode at a time. Starting with the bottom electrode. When water starts to flow either the obstruction flushed into the flowcell or the electrode just removed was the cause. Re-membrane if needed. Dry the flowcell before re-inserting the electrode.

15 (From Step 9) Connect the syringe with water to the sample probe tip. Reconnect the Reference electrode Waste line. Apply a slight pressure to the syringe. Look for water entering a flowcell, electrode cap, or leaking from the interconnect tubing. Replace the membrane, or tubing as required.

If the above does not identify the problem, please contact your Nova Service Representative.

NOTES:

8.1.1 Water (Flow) Test

The water (flow) test verifies that fluid can be pulled through the system from the probe. If water cannot be pulled through the system, a clog, leak, or mechanical pump problem exists.

1. From the Home screen, press Menu (soft key)
2. Press Service (soft key).
3. From the Service screen, select System Test. Then press Enter.
4. Move the sampler to the syringe position by using the arrow keys at the bottom right corner of the key pad.
    a. Select Sampler.
    b. Press Enter.
    c. Select Syringe.
    d. Press Enter.
5. Open the waste valve by using the arrow keys at the bottom right corner of the keypad.
    a. Select waste valve
    b. Press Enter. (Valve toggles to open position if closed.)
6. Turn the pump on to fast speed by using the arrow keys at the bottom right corner of the key pad.
    a. Select Pump.
    b. Press Enter.
    c. Select Fast.
    d. Press Enter.
7. Fill a 2 mL sample cup with water.
8. Open the door.
9. Insert the probe into the cup of water and observe for water being aspirated.

If water is NOT aspirated from the cup, then go to the **Pump Test** to check waste aspiration.
If water is aspirated from the cup, then the sample probe, sensor module, external tubing, and waste line are functioning with no blockage. The problem exists between the reagent pack and fluid fountain. Call Nova Service.

NOTES:

8.1.2 Pump Test

The pump test verifies that the pump is working properly and is capable of providing suction to the sensor module and probe.
If already on the System Test screen, skip to Step 4., otherwise, start with Step 1 below.

1. From the Home Screen, press Menu (soft Key)
2. Press Service (soft key).
3. From the Service screen, select System Test. Then press Enter.
4. Move the sampler to the syringe position by using the arrow keys at the bottom right corner of the keypad.
    a. Select Sampler.
    b. Press Enter.
    c. Select Syringe.
    d. Press Enter.
5. Open the waste valve by using the arrow keys at the bottom right corner of the keypad.
    a. Select Waste Valve.
    b. Press Enter. (Valve toggles to open position if closed.)
6. Turn pump to fast speed by using the arrow keys at the bottom right corner of the key pad.
    a. Select Pump.
    b. Press Enter.
    c. Select Fast.
    d. Press Enter.
7. To check the W-line for aspiration, fill a 2 mL sample cup with water.
8. Remove the tubing from the waste port of the reference electrode and place the waste tubing in the cup of water.
9. Observe for water being aspirated.

If water is aspirated during the pump test and not in the water (flow) test, there is a blockage or leak between the reference electrode, the sensor module, air detector, and probe. **Proceed to the Flow Path Flush Procedure**.
If water is not aspirated during the pump test, the problem is with the W-line, waste valve, pump, or waste bag. **Proceed to Step 10 below**.

NOTES:

10. If water is not aspirated, lift the waste tubing out of the waste valve. If flow starts, the tubing may have been collapsed or pinched, or the waste valve may be dirty or not working. Correct the problem. (Clean, if necessary, or call Nova service)
11. If flow does not start, remove the waste line from the front panel connection below the pump. Be ready to catch any water that is expelled from the tubing.
    If water flows from this tube there is a plug in the internal waste tubing or waste bag of the reagent pack.
12. Turn off the pump by using the arrow keys at the bottom right corner of the keypad.
    a. Select the Pump.
    b. Press Enter.
    c. Select Stop.
    d. Press Enter.
13. Connect a syringe (Probe Cleaning Syringe PN 02702) filled with water, that has a length of tubing attached, to the waste port on the front panel. Attempt to inject water through the line to clear the plug.
14. If there is not flow, remove the reagent pack to ensure the problem is not a poorly seated or damaged waste connection. Should the problem continue call Nova Service.
15. If the problem is resolved, reconnect the correct ends of the W-line to the waste port on the front panel and on the waste port of the reference electrode.
    Also position the tubing back into the waste valve.
16. Rerun the water test to verify proper flow.

NOTES:

8.1.3 Flushing Sensor Module, Air Detector, and Probe

If already on the system test screen, skip to Step 4, otherwise, start with Step 1 Below.

1. From the Home Screen, press menu (soft Key)
2. Press Service (soft key).
3. From the Service screen, select System Test. Then press Enter.
4. Move the sampler to the syringe position, if not already there, by using the arrow keys at the bottom right corner of the keypad.
    a. Select Sampler.
    b. Press Enter.
    c. Select Syringe.
    d. Press Enter.
5. Remove the W-line tubing from the waste port of the reference electrode.
6. Connect a syringe (Probe Cleaning Kit PN 02702) filled with water, that has a length of tubing attached, to the waste port of the reference electrode (see Figure 8.1).

NOTE: *The probe should still be in the syringe position.*

WARNING: *Water may spray out of the probe.*

7. Gently push the water through the reference electrode, sensor module, air detector, and probe. If the flow path is clear, the plunger can be depressed with no resistance, otherwise, resistance will be felt. The blockage may be dislodged by pushing the water through the flow path. If not, flush the suspected individual components by proceeding to the Flushing the Reference Electrode procedure (Section 5.5.4).
8. When the blockage is cleared, a nice steady stream of water should be seen coming out of the probe.
9. Rerun the water test to verify proper flow. The Sampler should be in the syringe position.
    a. Turn pump to fast speed.
    b. Open waste valve.
    c. Insert the probe into a cup of water and observe for water being aspirated.

    If water flowed freely during the flush procedure but still does not pass the water test, then air is entering the system preventing aspiration.

NOTES:

a. Verify interconnect tubing is properly connected. Reseat if necessary.
b. Inspect the seal between the reference electrode and sensor module. Replace interconnect tubing, if necessary.
c. Inspect each sensor to assure internal fill solution is at the proper level. If not replace cap.
d. Inspect pH sensor to assure glass tip is not broken. Replace sensor, if necessary

10. Rerun the water test.
11. Once proper flow has been established, turn the pump off. Use the arrow keys at the bottom right corner of the keypad.
    a. Select pump.
    b. Press Enter.
    c. Select Stop.
    d. Press Enter.
12. Move the sampler back to the Home position. Use the arrow keys at the bottom right corner of the keypad.
    a. Select Sampler.
    b. Press Enter.
    c. Select Home.
    d. Press Enter.
13. Close the waste valve by using the arrow keys at the bottom right corner of the keypad.
    a. Select waste valve.
    b. Press Enter (valve toggles to closed position if open).
14. Press Home (soft key).

8.1.4 Flushing the Reference Electrode

1. Remove the W-line and R-line from the reference electrode.
2. Lift the reference electrode off the sensor module by pulling up on the locking pin that is on the top of the reference electrode.
3. Connect a syringe (Probe Cleaning Syringe PN 02702) filled with water, that has a length of tubing attached to it, to the W-port of the reference electrode. While covering the R-port with your finger, push water through the electrode so that the water flows out of the flow cell port. Repeat by attaching the syringe to the R-port and covering the W-port while pushing water through the electrode.
4. Reinstall the reference electrode.

NOTES:

8.2 Flushing the Entire Flow Path

Flush flow path when a flow problem has been detected. Typical flow problem error codes are Insufficient Sample, No Std A, B, C, or D Fluid.

Flush individual components **only** if the problem is not cleared by a flow path flush.

WARNING: *Use appropriate protective face shields, gloves, etc., when attempting to flush, clean, or handle any components of the analyzer which come in contact with blood specimens.*

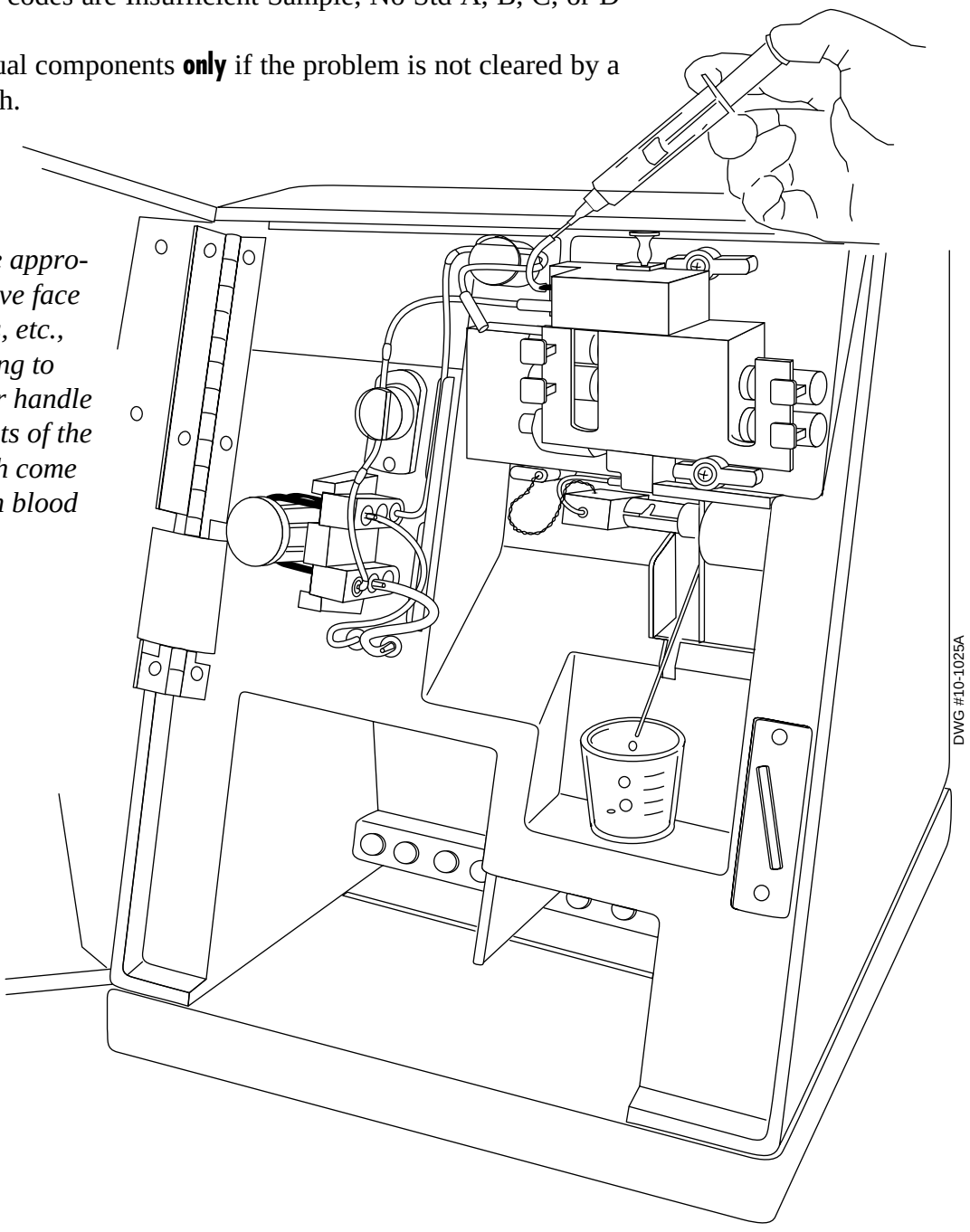


Figure 8.1 Flow Path Air Flush

Flushing the Flow Path Checklist

NOTES:

WARNING: *Use appropriate protective face shields, gloves, etc., when attempting to flush, clean, or handle any components of the analyzer which come in contact with blood specimens.*

☐ Step 1 Initiate Flowpath maintenance.

- Press Menu (soft key) on the Home screen.
- The Operational Menu screen appears.
- Select Service Menu (soft key); enter password, if enabled.
- Select System Test. Press Enter.
- Select **Sampler** by moving the cursor with the arrow keys. Then press Enter.
- Select syringe by moving the cursor with the arrow keys. Then press Enter.
- Open the door.

☐ Step 2 Prepare syringe.

- Disconnect the W-line from the side of the reference electrode.
- Attach a length of tubing to the end of the Probe Cleaning Syringe (PN 02702).
- Pull back the plunger of the syringe to fill it with air.
- Attach the syringe tubing to the W-line port. (Refer to Figure 8.1, if necessary.)

☐ Step 3 Flush air through flow path.

- Press syringe plunger in slowly. If flow path is clear, the plunger can be depressed with **no** resistance. If a clot or other obstruction is present, resistance will be felt. If necessary, repeat the procedure using deionized or distilled water.

NOTES:

☐ **Step 4 Determine results.**

- Continue to **Step 5** if the obstruction has been flushed free.
- If not, repeat flush procedure using deionized or distilled water or contact key operator of lab for assistance.

☐ **Step 5 End flush procedure if no other components need flushing.**

- Remove syringe.
- Reattach the W-line to the reference electrode.
- Press Exit (soft key) to return to the home position.
- Close the door.
- Press Home (soft key) twice to return to Home screen.

☐ **Step 6 Prime the flow path.**

- From the Home screen, press Menu (soft key).
- Select Flowpath/Probe maintenance. Then press Enter.
- Press Continue (soft key) to prime the flow path.

☐ **Step 7 Calibrate.**

- A pop-up screen appears to question - Do you want to recalibrate? Yes or No.
- Press Yes; calibration takes place.

NOTE: *If No is pressed, you can still recalibrate. From the Home screen, press Calibrate (soft key) to recalibrate analyzer.*

- Contact key operator (or lab) for assistance if problem is not resolved.

NOTES:

8.3 Reference Solution Test

1. Press Menu (soft key) on the Home screen.
2. The Operational Menu screen appears.
3. Select Service Menu (soft key); enter password, if enabled.
4. Select System Test. Press Enter.
5. Using the arrow keys, highlight Ref Valve.
6. Press Enter to toggle from Closed to Open.
7. Using the arrow keys, highlight Pump.
8. Press Enter and select Fast using the arrow keys.
9. Press Enter.
10. Open the door and disconnect the R-tubing from the reference electrode.
11. Hold the R-tubing over a piece of gauze or sample cup to catch any solution that may flow out of the tubing.
12. Reference solution should flow at a minimum of 1 drop per second.
13. If there is flow, turn off the pump.
    If there is no reference solution dripping out of the tubing, verify there is reference solution or a blockage. Check for blockage in the reference tubing or the pump harness tubing. If necessary, replace the reagent pack.

NOTES:

9 Maintenance

9.1 Logging Maintenance

The Stat Profile pHOx Maintenance Log (PN 22362) contains each of the following types of log sheets — maintenance, quality control, and service record.

9.1.1 Maintenance Log Sheets

Allows the operator to record the daily and preventive maintenance procedures. A sample is shown.

MAINTENANCE LOG

Month/Year_____ Analyzer #_____	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Deproteinize Sample Preheater (PN 12704) as needed																
Reposition Tubing in Pinch Valves Weekly																
Other																

PERFORMANCE DATA LOG		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Record Electrode Slopes Weekly:	pH																
	P_{CO_2}																
	P_{O_2}																
	Na^+																
	S_{O_2}																
	Hct																

MAINTENANCE LOG

Month/Year_____ Analyzer #_____	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Deproteinize Probe/Sensor Module (Use PN 12704) as needed															
Reposition Tubing in Pinch Valves Weekly															
Clean the S_{O_2} Sensor Every 3 Months	Initial and Date When Done. Tech's Initial's_____ Date_____														
Change the Pump Tubing Every 3 Months	Initial and Date When Done. Tech's Initial's_____ Date_____														
Change the R-Line and W-Line Every 3 Months	Initial and Date When Done. Tech's Initial's_____ Date_____														
Other															

PERFORMANCE DATA LOG		17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Record Electrode Slopes Weekly:	pH															
	P_{CO_2}															
	P_{O_2}															
	Na^+															
	S_{O_2} (LED1)															
	Hct															

Figure 9.1 Maintenance Schedule and Performance Data Log

QUALITY CONTROL LOG

Controls	Assay Range			Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	Low	Mean	High																	
Level 1 PN 22760				pH																
Lot # _____				PCO_2																
Exp. Date _____				PO_2																
				SO_2																
				Hct																
				Hb																
Level 2 PN 22761				pH																
Lot # _____				PCO_2																
Exp. Date _____				PO_2																
				pH																
Level 3 PN 22762				PCO_2																
Lot # _____				PO_2																
Exp. Date _____				SO_2																
				Hct																
				Hb																
TECHNICIAN'S INITIALS																				

Figure 9.2 Quality Control Log

NOTES:

SERVICE RECORD

NOTE: Record serial/lot number of components

Date	Nature of Problem	Resolution/Comments

Figure 9.3 Service Record

NOTES:

10 Routine Maintenance

10.1 Overview

How often maintenance procedures are done is in part dependent on how much the instrument is in use.
Each schedule includes daily, weekly, monthly, every 3 months, and annual procedures.
The **Stat Profile pHOx Maintenance Log** helps you remember when to do each procedure. It contains the daily and preventative maintenance log sheets, quality control log sheets, and service record log sheets.

NOTE: *Make sure to use the correct maintenance log sheet. The maintenance log sheets list procedures due for each month.*

10.2 General Maintenance Procedures

See the **Maintenance Planner** (Quick Reference) for daily, weekly, monthly, quarterly, and annual procedures.
Changes in the timing of these procedures should be made according to the number of samples per day, the quality of the samples, and the lab circumstances encountered. Consult with the Nova Hot Line at 1-800-545-NOVA if you have any questions.

NOTES:

10.2.1 Suggested Daily Start-up Procedure

✔ "Housekeeping" Procedures

Discuss modifying this to meet lab situation.

Verify reagent and control levels.
Review Maintenance Logs for procedures due.

✔ Analyze Controls (Level 1, 2, and 3).

✔ Document QC.

10.2.2 Flowpath Cleaning/Deproteinizing

1. **Deproteinizing Solution** (PN 12704) - used for routine cleaning) is packaged in ampules. Use this solution when routine cleaning is required.

The cleaning cycle:

- Removes protein buildup
- Frequency depends on the number of samples or the condition of those samples
- Should be performed when the hematocrit sensor is uncalibrated
- Must be followed by a full calibration
- Takes 5 minutes
- Can be run at the end of a shift or when most convenient
- Remove the sodium sensor and install a blank.

See **Flowpath Cleaning Procedure Checklists.**

Flowpath Cleaning Procedure Checklist

NOTES:

☐ Step 1 Remove the Na^+ sensor.

- Select Flowpath/Probe Maintenance; wait until system is finished removing fluid from the flow path.
- Open the door and remove the Na^+ sensor. (Squeeze the front and rear of the black body {sensor clip} and gently pull it out of the sensor module.)
- Replace it with a blank sensor.
- Press Cancel.
- At pop-up screen, press Cancel again.

☐ Step 2 Begin sample preheater cleaning procedure.

- Press Menu (soft key on the Home screen) to display Operational Menu.
- Select Flowpath Cleaning.
- Probe extends for aspiration.

☐ Step 3 Prepare solution.

- Open an ampule of Deproteinizing Solution (PN 12704).

☐ Step 4 Present sample and begin cycle.

- Position the ampule over the extended probe.
- Press Continue (soft key) to aspirate the solution.

CAUTION: *Do not allow the sample probe to touch the bottom of the ampule.*

- When the system signals by an audible alarm, remove the ampule of deproteinizing solution.
- A pop-up screen appears when the aspiration is completed.

NOTES:

☐ **Step 5 Sequence begins.**

- Press Analyze.
- Discard any unused solution. Do not save it for use later.
- At the completion of the cycle, a pop-up screen appears questioning to recalibrate. Press NO.

☐ **Step 6 Replace the Na^+ sensor.**

- Press Menu.
- Select Flowpath/Probe Maintenance.
- Remove blank sensor.
- Install the Na^+ sensor.
- Press Continue.

☐ **Step 7 Calibrate.**

- At the completion of the Flowpath Priming Cycle, a pop-up screen appears questioning to Recalibrate.
  Press Yes.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

NOTES:

10.2.3 Flow Cell Conditioning

- Decreases bubble hang-up in the flow cell and at the sensor tips by wetting the flow cell.
- Coats the sensor membranes with protein to improve their performance.
- Perform during periods of infrequent sampling and after flow cell replacement, PO_2 or PCO_2 sensor maintenance, and troubleshooting.
  Takes 5.5 minutes.

See **Flow Cell Conditioning Cycle Checklist.**

Flow Cell Conditioning Checklist

NOTES:

☐ Step 1 Prepare sample.

- Fill a 2 mL sample cup 1/2-full with heparinized whole blood (or serum) or select a syringe containing at least 1 mL of heparinized whole blood.

☐ Step 2 Begin flow cell conditioning cycle.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Select Sensor Conditioning.
- Press Enter

☐ Step 3 Present sample and begin sequence.

- Pour whole blood (or serum) into a cup.
- Position the cup over the extended probe.

CAUTION: *Do not allow the sample probe to touch the bottom of the cup.*

- Press Continue (soft key).
- After the audible alarm, remove the cup.
- Press Analyze. The probe moves downward.
- The sequence begins. Whole blood fills the entire flow path.
- Conditions for 5 minutes. Then flushes the flow cell.

☐ Step 5 Calibrate.

- At the completion of the cycle, a pop-up screen appears questioning to recalibrate. Press Yes to recalibrate.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

NOTES:

11 Maintaining Sensors

11.1 Overview

- Correctly functioning sensors are key to obtaining accurate results.
- Maintenance is essential for sensors to function correctly.
- Frequency of conditioning or replacement is dependent on the number of samples per day and will vary from lab to lab.
- Monitoring trends and shifts or both in control values and sensor slope values using your logbook is the best way to determine an appropriate maintenance interval for your laboratory.
- Use the maintenance checklists to do preventive maintenance or to correct problems.

Before replacing sensors, membranes, etc.:

- Press Menu (soft key) from the Home screen. Then select Flowpath/Probe Maintenance. Press Enter.
- Remove sensor and shake down.
- Dry sensor and flow cell chamber.
- Reseat sensor.
- Perform calibration.

Table of Contents Manual

This section contains maintenance procedures for the Stat Profile pHOx Analyzer sensors. These procedures are done as part of a preventive maintenance program or when a problem occurs. The procedures can be used during training or for reviewing on your own.

Maintaining Sodium (Na^+) 11-3
pH Sensors 11-5
Maintaining PCO_2 Sensor 11-8
Maintaining PO_2 Sensor 11-12
Maintaining SO_2 11-17

WARNING

Use appropriate protective face shields, gloves, etc., when attempting to flush, clean, or handle any components of the analyzer which come in contact with blood specimens.

Na^+ Maintenance Checklist

NOTES:

When Change the Sodium (Na^+) sensor when it has problems with slope, instability, overload, or drift.

What You Need Sodium sensor (PN 21523)
Stat Profile pHOx Controls

Stat Profile pHOx Maintenance Log (PN 22362)
Cotton swabs

☐ Step 1 Record slope for comparison purposes.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the Na Calibration & Analysis Data is displayed.
- Press Print (soft key) to print the slope information. Save for comparison in **Step 7.**
- Press Exit (soft key) twice to return to the Operational Menu screen.

☐ Step 2 Begin Na^+ maintenance.

- Select Flowpath/Probe Maintenance.
- Wait until system is finished removing fluid from the flow path.
- Open the door.
- Remove the Na^+ sensor by squeezing the front and rear of the black body (sensor clip) and gently pulling it out of the sensor module.

CAUTION: Do Not condition the Na^+ sensor; you will destroy the sensor.

NOTES:

☐ **Step 3 Clean and dry the sensor module cuvette with a cotton swab.**

☐ **Step 4 Replace with a new sensor.**

- Insert a new Sodium Sensor (PN 21523).

TRAINING CLASS ONLY — Continue with the next sensor.

☐ **Step 5 Prime the flow path.**

- Close the door.
- Press Continue (soft key) to prime the flow path.

☐ **Step 6 Calibrate.**

- At the completion of the cycle, a pop-up screen appears questioning to recalibrate. Press Yes to recalibrate.
- Calibration begins.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

NOTES:

☐ Step 7 Review calibration status and slope performance number.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the Na^+ Calibration & Analysis Data is displayed.
  Compare current versus previous slope performance numbers saved from **Step 1.**
  If higher and within range, continue with **Step 8.**
  or
  If not, replace sensor**.**

☐ Step 8 Verify sensor performance by running controls.

- Run QC samples, 3 levels.

CAUTION: *Controls should be stored at approximately 25°C.*

- Verify controls are in range by comparing with data insert sheet or within lab criteria.

- Record procedure and document quality control results.

pH Maintenance Checklist

NOTES:

When

Condition the pH sensor when the sensor fails to calibrate because of low slope or when pH control results are high.

What You Need

pH Sensor Conditioning Solution (PN 23397)
Sensor Conditioning Holder (PN 09458)
Stat Profile pHOx Controls Multipack (PN 22763)

Stat Profile pHOx Maintenance Log (PN 22362)
Lint-free tissues
Cotton swabs
Deionized or distilled water

☐ Step 1 Record slope for comparison purposes.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the pH Calibration & Analysis Data is displayed.
- Press Print (soft key) to print the slope information. Save for comparison in **Step 7.**
- Press Exit (soft key) twice to return to the Operational Menu screen.

☐ Step 2 Begin pH maintenance.

- Select Flowpath/Probe Maintenance.
- Wait until system is finished removing fluid from the flow path.
- Open the door.
- Remove the pH sensor by squeezing the front and rear of the black body (sensor clip) and gently pulling it out of the sensor module.

NOTES:

☐ Step 3 Condition glass tip, replace, and reconnect sensor. (Troubleshooting Only)

- Fill bottom chamber of sensor conditioning holder (PN 09458) with pH conditioning solution (PN 23397).
  Immerse sensor tip in conditioning solution to soak. The pH sensor is conditioned for 15 minutes.
- Remove sensor.
  Rinse tip with deionized water.
- Dry tip with lint-free tissue.
  Dry flow cell with cotton swab covered with lint-free tissue.
- Reinsert sensor.

TRAINING CLASS ONLY — Continue with the next sensor.

☐ Step 4 Prime the flow path.

- Close the door.
- Press Continue (soft key) to prime the flow path.
- When the priming is completed, a pop-up screen appears to question for recalibration. Press No.

☐ Step 5 Condition the flow cell.

- From the Operational Menu, select Sensor Conditioning.

NOTE: *All sensors must be in the flow cell during a Flow Cell Conditioning cycle.*

- Fill a 2 mL sample cup 1/2-full with whole blood.
- Insert the probe into the blood.
- Press Continue (soft key) to aspirate the blood.
- After the audible alarm, remove the cup.
- Press Analyze on the pop-up screen. The probe moves downward. The sequence begins. Whole blood fills the entire flow path. Conditioning is a 5.5 minute cycle. Then the system flushes the flow cell.

NOTES:

☐ Step 6 Calibrate.

- At the completion of the cycle, a pop-up screen appears questioning to recalibrate. Press Yes to recalibrate.
- Calibration begins.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

☐ Step 7 Review calibration status and slope performance number.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the pH Calibration & Analysis Data is displayed.
  Compare current versus previous slope performance numbers saved from **Step 1.**
  If higher and within range, continue with **Step 8.**
  or
  If not, replace sensor**.**

☐ Step 8 Verify sensor performance by running controls.

- Run QC samples, 3 levels.

CAUTION: *Controls should be stored at approximately 25°C.*

- Verify controls are in range by comparing with data insert sheet or within lab criteria.
- Record procedure and document quality control results.

PCO_2 Maintenance Checklist

NOTES:

When

Change the membrane for low slope, controls out of range, and PCO_2 instability, drift, or overload error codes.

What You Need

PCO_2 Membraned Cap Kit (PN 25048)
Stat Profile pHOx Controls Multipack (PN 22763)

Stat Profile pHOx Maintenance Log (PN 22362)
Lint-free tissues
Cotton swabs
Deionized or distilled water
Heparinized whole blood

☐ Step 1 Record slope for comparison purposes.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the PCO_2 Calibration & Analysis Data is displayed.
- Press Print (soft key) to print the slope information. Save for comparison in **Step 12.**
- Press Exit (soft key) twice to return to the Operational Menu screen.

☐ Step 2 Begin PCO_2 Sensor Membraning and Replacement

- Select Flowpath/Probe Maintenance.
- Wait until system is finished removing fluid from the flow path.
- Open the door.
- Remove the PCO_2 Sensor by squeezing the front and rear of the black body (sensor clip) and gently pulling it out of the sensor module.

NOTES:

Step 3 Separate cap and membrane from sensor.

- Unscrew the used membrane cap from the sensor body and discard it. **Dispose of the plastic cap as a biohazard**.

CAUTION: *If installing a new sensor, carefully remove the shipping cap before installing a new membrane cap. Do not touch the electrical contacts of the sensor.*

Step 4 Replace membrane cap on sensor.

NOTE: *The prefilled PCO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the biosensor's performance.*

- Open foil pouch by tearing at score mark on the bottom of the package.
- Take a new PCO_2 Membrane Cap (PN 25048) that is prefilled with internal filling solution. Hold the shipping plug end of the membrane cap and shake it gently, as if shaking down a thermometer, to ensure that the air bubble is at the threaded end of the membrane cap.
- Unscrew the black shipping plug from the cap. Screw the cap onto the sensor. Discard the black shipping plug. Do not tilt the membrane cap when installing onto the sensor; the internal filling solution may drip out.

CAUTION: *Do not touch the surface of the membrane.*

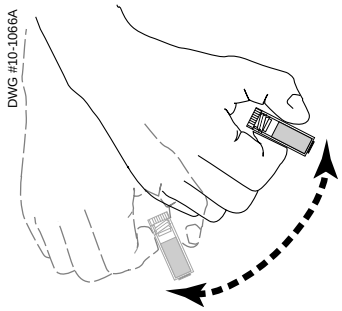


Figure 11.1 Shaking Down Membrane Cap

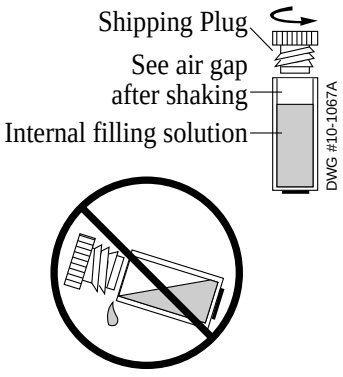


Figure 11.2 Membrane Cap

Step 5 Check for air bubbles at the tip of sensor.

- If new sensor, remove from the foil pack.
- Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
- With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.

CAUTION: *Do not point sensor tip upward.*

NOTES:

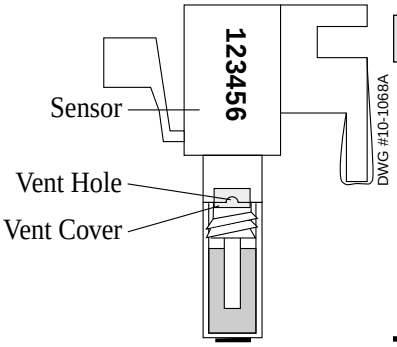


Figure 11.3 PCO_2 sensor with vent hole covered

Step 6 Dry the sensor and membrane.

- Wipe the sensor body and cap dry.
- Remove a single vent cover from the blue backing and place over the vent hole.
- Press firmly to ensure a good seal.

Step 7 Clean the sensor module cuvette with a cotton swab.

Step 8 Replace and reconnect sensor.

- Insert the sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.

STOP

TRAINING CLASS ONLY —Continue with the next sensor.

Step 9 Prime the flow path.

- Close the door.
- Press Continue (soft key) to prime the flow path.
- When the priming is completed, a pop-up screen appears to question for recalibration. Press No. The analyzer returns to the Operational Menu.

Step 10 Condition the sensor module.

NOTE: *All sensors must be in the sensor module during a Sensor Conditioning cycle.*

- Fill a 2 mL sample cup 1/2-full of whole blood.
- Select Sensor Conditioning from the Operation Menu and press Enter.
- Immerse the probe in the whole blood.
- Press Continue (soft key) to aspirate the blood.
- After the audible alarm, remove the cup.

NOTES:

- Press Analyze on the pop-up screen. The probe moves downward. The sequence begins. Whole blood fills the entire flow path. Conditioning is a 5.5 minute cycle. Then the system flushes the flow cell.

☐ Step 11 Calibrate.

- At the completion of the cycle, a pop-up screen appears questioning to recalibrate. Press Yes to recalibrate.
- Calibration begins.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

☐ Step 12 Review calibration status and slope performance number.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the PCO_2 Calibration & Analysis Data is displayed.
  Compare current versus previous slope performance numbers saved from **Step 1.**
  If higher and within range, continue with **Step 13.**
  or
  If not, replace sensor**.**

☐ Step 13 Verify sensor performance by running controls.

- Run QC samples, 3 levels.

CAUTION: *Controls should be stored at approximately 25°C.*

- Verify controls are in range by comparing with data insert sheet or within lab criteria.
- Record procedure and document quality control results.

PO_2 Maintenance Checklist

NOTES:

When

You will need to polish and remembrane the oxygen (PO_2) sensor if you are experiencing a problem such as slope out of range, controls out of range, or drift error codes on analysis.

What You Need

PO_2 Premembraned Cap Kit (PN 21795)
Stat Profile pHOx Controls Multipack (PN 22763)

Stat Profile pHOx Maintenance Log (PN 22362)
Polishing paper
Lint-free tissues
Cotton swabs
Deionized or distilled water
Heparinized whole blood

☐ Step 1 Record slope for comparison purposes.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the PO_2 Calibration & Analysis Data is displayed.
- Press Print (soft key) to print the slope information. Save for comparison in **Step 13.**
- Press Exit (soft key) twice to return to the Operational Menu screen.

☐ Step 2 Begin PO_2 Sensor Polishing, Membraning, and Replacement

- Select Flowpath/Probe Maintenance.
- Wait until system is finished removing fluid from the flow path.
- Open the door.
- Remove the PO_2 Sensor by squeezing the front and rear of the black body (sensor clip) and gently pulling it out of the sensor module.

NOTES:

Step 3 Separate cap and membrane from sensor.

- Unscrew the used membrane cap from the sensor body and discard it.
  Dispose of the plastic cap as a biohazard.

Step 4 Polish the sensor (Troubleshooting only).

- If troubleshooting, polish the sensor: if not, skip to Step 5.
- Take a polishing paper and place a couple of drops of deionized water onto it.
- Hold the PO_2 polishing paper so that the tip of your index finger provides light pressure against the back of the paper.
- Gently polish the sensor tip on the paper, move the tip in a circular motion for about 10 seconds.

CAUTION: *Never polish the sensor on a hard surface such as a bench top.*

- Discard the used polishing paper.
- Wipe the sensor tip with a lint-free tissue soaked in deionized water.

Step 5 Replace membrane cap on sensor.

- Open foil pouch by tearing at score mark on the bottom of the package.
- Take a new PO_2 Premembraned Cap (PN 21795) that is prefilled with internal filling solution, and shake it gently to ensure that the solution is away from the threaded end and at the membrane end. Unscrew and discard the shipping plug from the cap.
- Insert the sensor body straight down (vertical position only to ensure no loss of internal filling solution) into the filled cap and screw the cap onto the sensor body.

CAUTION: *Do not touch the surface of the membrane.*

The prefilled PO_2 cap does not require any additional filling solution. Do not add or remove any Internal Filling Solution. The prefilled level of solution is all that is needed to operate the analyzer successfully. Adding or subtracting from the prefilled level will effect the biosensor's performance.

NOTES:

☐ **Step 6 Check for air bubbles at the tip of sensor.**

- Hold the sensor with the cap downward. With a wrist-snapping motion, shake the sensor down to move air bubbles to the back of the sensor.
- With the sensor tip still downward, observe the tip for bubbles. If bubbles are present, tap the sensor with a finger to loosen the bubbles and again shake the sensor down. Repeat if necessary.

CAUTION: *Do not point sensor tip upward.*

☐ **Step 7 Dry the sensor and membrane.**

- Dry the sensor with a lint-free tissue.
- Do not touch the membrane.

☐ **Step 8 Clean the sensor module cuvette with a cotton swab.**

☐ **Step 9 Check for air bubbles, replace and reconnect sensor.**

- Remove air bubbles by repeating **Step 6.**
- Insert the sensor into the sensor module by sliding the sensor body into the sensor module until the sensor clips into place.

TRAINING CLASS ONLY —Continue with the next sensor.

NOTES:

☐ Step 10 Prime the flow path.

- Close the door.
- Press Continue (soft key) to prime the flow path.
- When the priming is completed, a pop-up screen appears to question for recalibration. Press No. The analyzer returns to the Operational Menu.

☐ Step 11 Condition the sensor module.

NOTE: *All sensors must be in the sensor module during a Sensor Conditioning cycle.*

- Fill a 2 mL sample cup 1/2-full of whole blood.
- Select Sensor Conditioning from the Operation Menu and press Enter.
- Immerse the probe in the whole blood.
- Press Continue (soft key) to aspirate the blood.
- After the audible alarm, remove the cup.
- Press Analyze on the pop-up screen. The probe moves downward. The sequence begins. Whole blood fills the entire flow path. Conditioning is a 5.5 minute cycle. Then the system flushes the flow cell.

☐ Step 12 Calibrate.

- At the completion of the cycle, a pop-up screen appears questioning to recalibrate. Press Yes to recalibrate.
- Calibration begins.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

- Recalibrate a second time: from the Home screen, press Calibrate (soft key) then press ENTER.

NOTES:

☐ Step 13 Review calibration status and slope performance number.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the PO_2 Calibration & Analysis Data is displayed.
  Compare current versus previous slope performance numbers saved from **Step 1.**
  If higher and within range, continue with **Step 14.**
  or
  If not, replace sensor**.**

☐ Step 14 Verify sensor performance by running controls.

- Run QC samples, 3 levels.

CAUTION: *Controls should be stored at approximately 25°C.*

- Verify controls are in range by comparing with data insert sheet or within lab criteria.
- Record procedure and document quality control results.

SO_2 Maintenance Checklist

When

You will need to clean the SO_2 sensor surface and flow cell chamber every 3 months. Replace sensor with recurring status codes after recalibrations.

What You Need

SO_2 Calibrators Multipack (PN 17371)
Stat Profile pHOx Controls Multipack (PN 22763)
Stat Profile pHOx Maintenance Log (PN 22362)
Lint-free tissues
Bleach
Deionized water

NOTES:

Anytime the SO_2 cable is removed from the flow cell, a calibration is needed,

☐ Step 1 Record slope for comparison purposes.

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the SO_2 Calibration & Analysis Data is displayed.
- Press Print (soft key) to print the slope information. Save for comparison in **Step 6.**
- Press Exit (soft key) twice to return to the Operational Menu screen.

☐ Step 2 Clean SO_2 sensor surface.

- Select Flowpath/Probe Maintenance.
- Wait until system is finished removing fluid from the flow path.
- Open the door.
- To remove the sensor, unscrew the lead screw and pull out.
- Clean the sensor surface with a lint-free tissue that is soaked with preheater cleaning solution or a solution of 10% bleach.
- Rinse with deionized water and blot dry.

NOTES:

☐ **Step 3 Reinstall fiber optic cable.**

- Clean the sensor module cuvette using a cotton-tipped applicator.
- Reinstall the sensor and tighten the lead screw.

☐ **Step 4 Prime the flow path.**

- Close the door.
- Press Continue (soft key) to prime the flow path.

☐ **Step 5 Calibrate.**

- At the completion of the priming cycle, a pop-up screen appears questioning to recalibrate. Press Yes to recalibrate.
- Calibration begins.

NOTE: *If no is pressed, the analyzer returns to the Operational Menu screen. Press Home (soft key). To calibrate on this screen, press Calibrate (soft key).*

☐ **Step 6 Review calibration status and slope performance number.**

- Press Menu (soft key on the Home screen) to display the Operational Menu screen.
- Press Service (soft key) and enter your password to display the Service Menu screen.
- Select Sensor Subsystem, press Enter, and press Next Page (soft key) until the SO_2 Calibration & Analysis Data is displayed.
  Compare current versus previous slope performance numbers saved from **Step 1.**

NOTES:

☐ Step 7 Verify sensor performance by running controls.

- Run QC samples, 3 levels.

CAUTION: *Controls should be stored at approximately 25°C.*

- Verify controls are in range by comparing with data insert sheet or within lab criteria.
- Record procedure and document quality control results.

NOTES:

NOTES:

12 Periodic Maintenance

- Pump tubing
- R-line
- W-line
- Probe
- Air detector

12.1 Replacement of Pump Tubing, R-Line, and W-Line

Instructor: demonstrates and observes trainees replacing the tubing.

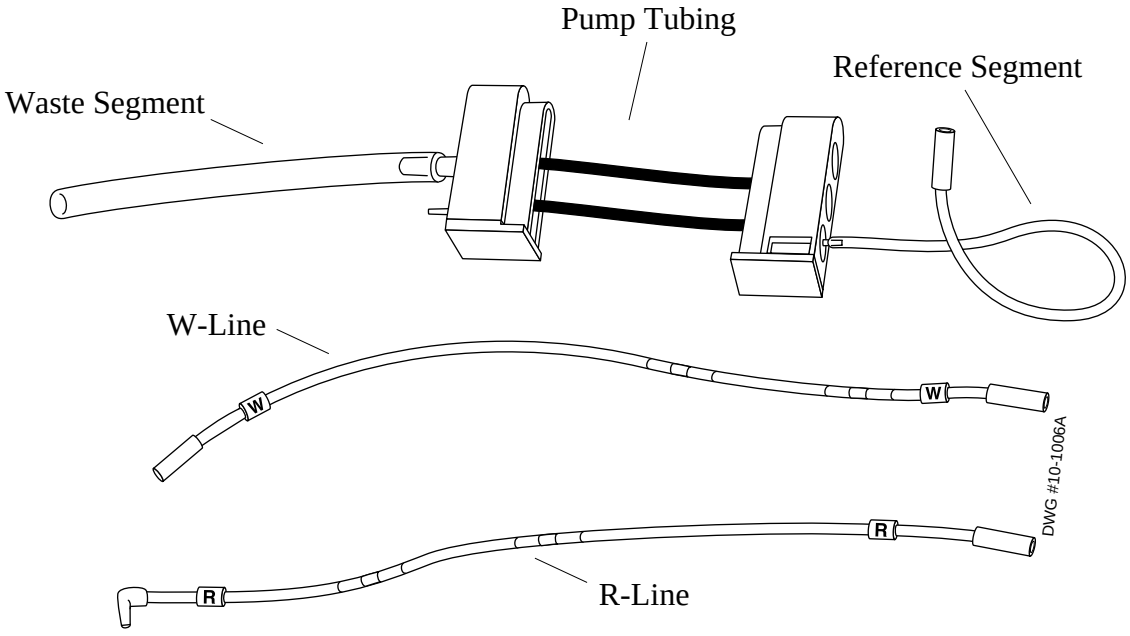


Figure 12.1 Replacing the Harnesses

NOTES:

12.1.1 Pump Tubing Replacement

The tubing that goes around the pump can be replaced by following this procedure.

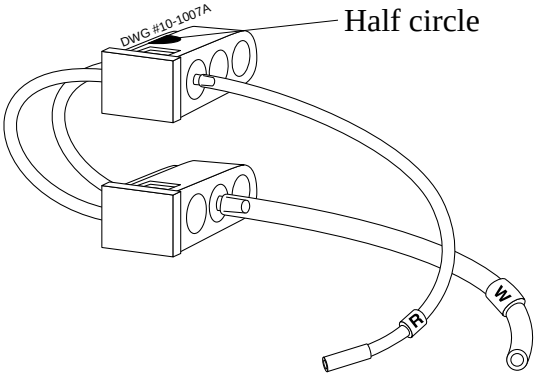
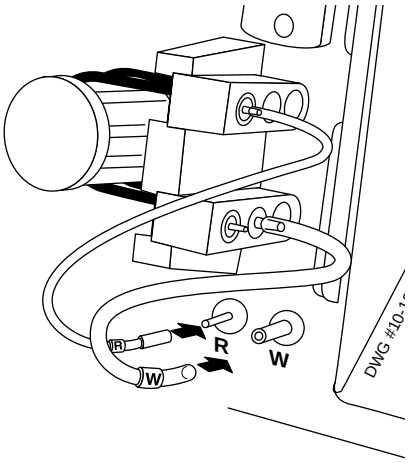


Figure 12.2 Pump Tubing

1. From the Operation Menu screen, select Flow Path Maintenance and press Enter.
2. Open the door.
3. Disconnect the R-line and W-line (the ones that go through the pinch valves) from the pump manifold.
4. Disconnect the R and W-pump tubing lines from the labeled outlets that are below the pump manifold.
5. Slide the top and bottom tube manifolds out
6. Discard the used tubing and manifolds.
7. On the new pump tubing, Locate the half circle on one of the manifolds. This is the top manifold.



8. Slide the top pump tubing manifold into its slots. The top manifold's half circle should line up with the half circle on the slot.
9. Stretch the pump tubing around the pump and slide the bottom manifold into its slots.
10. Connect the R-pump tubing line to the R-labelled outlet below the pump manifold (see Figure 12.3).
11. Connect the W-pump tubing line to the W-labelled outlet below the pump manifold (see Figure 12.3).
12. Reconnect the R-line and W-line (the ones that go through the pinch valves) to the pump manifold.
13. Close the door and press the Continue key (soft key).
14. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.

Figure 12.3 Connecting the Pump Tubing W and R-lines

NOTES:

12.1.2 Waste Line Replacement

The waste line should be replaced at intervals prescribed in the maintenance log. The W-line connects at the middle of the top pump manifold, travels through the waste pinch valve, and connects to the top W-labelled outlet on the reference electrode. The W-line can be replaced by following this procedure.

1. From the Operation Menu screen, select Flow Path Maintenance and press Enter.
2. Open the door.
3. Disconnect the W-line from the pump manifold, pinch valve, and reference electrode.
4. Attach the new W-line starting with the pinch valve. At the pinch valve segment of the W-line (elastic segment), stretch the segment and slide it into the pinch valve.
5. Connect the line to the W-labelled outlet of the reference electrode and the middle of the top pump manifold. (See Figure 12.4.)

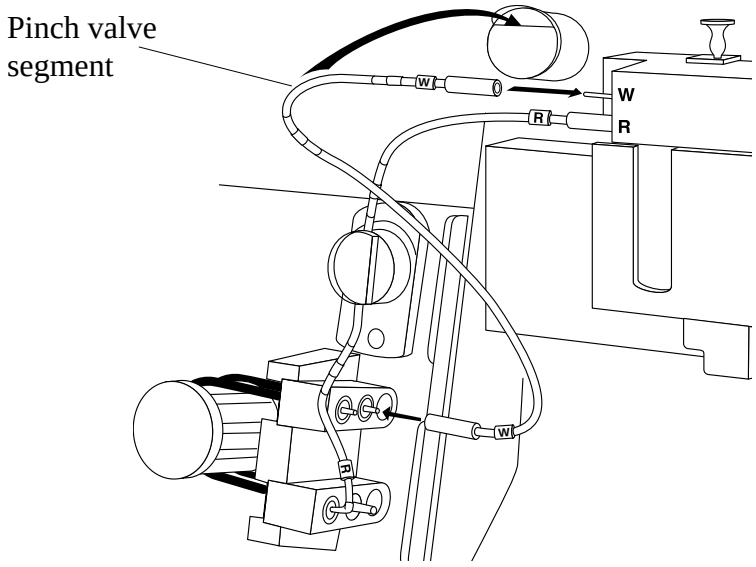


Figure 12.4 Connecting the W-line

6. Close the door and press the Continue key (soft key).
7. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.

NOTES:

12.1.3 Reference Line Replacement

The reference line should be replaced at intervals prescribed in the maintenance log. The R-line connects at the outside of the bottom pump manifold, travels through the reference pinch valve, and connects to the bottom R-labelled outlet on the reference electrode. The R-line can be replaced by following this procedure.

1. From the Operation Menu screen, select Flow Path Maintenance and press Enter.
2. Open the door.
3. Disconnect the R-line from the pump manifold, pinch valve, and reference electrode.
4. Attach the new R-line starting with the pinch valve. At the pinch valve segment of the R-line (elastic segment), stretch the segment and slide it into the pinch valve.
5. Connect the line to the R-labelled outlet of the reference electrode and the outside of the bottom pump manifold. (See Figure 12.5.)

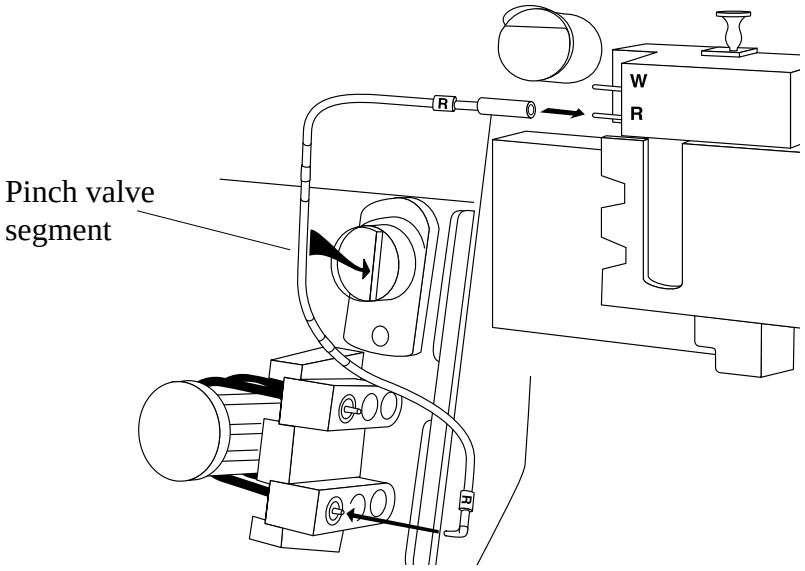


Figure 12.5 Connecting the R-line

6. Close the door and press the Continue key (soft key).
7. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.

NOTES:

12.2 Probe and Air Detector Replacement

Instructor: Demonstrate, then observe trainees doing Probe replacement.

When: As needed

1. From the Operation Menu screen, select Flow Path/Probe Maintenance and press Enter.

   NOTE: *If you are just changing the air detector, skip to Step 4.*

2. Press Move Probe (soft key). Open the door.
3. Remove the capillary adapter from the front of the probe. (See Figure 12.6.)
4. Disconnect the air detector's sample line from the sensor module.
5. Disconnect the 2-prong cable
6. If changing the probe, push the air detector down and pull the air detector with probe out of the sampler assembly. If changing only the air detector, push the air detector down and pull the air detector out. Replace with new air detector and skip to Step 9. DO NOT remove the probe if just the air detector is to be changed.

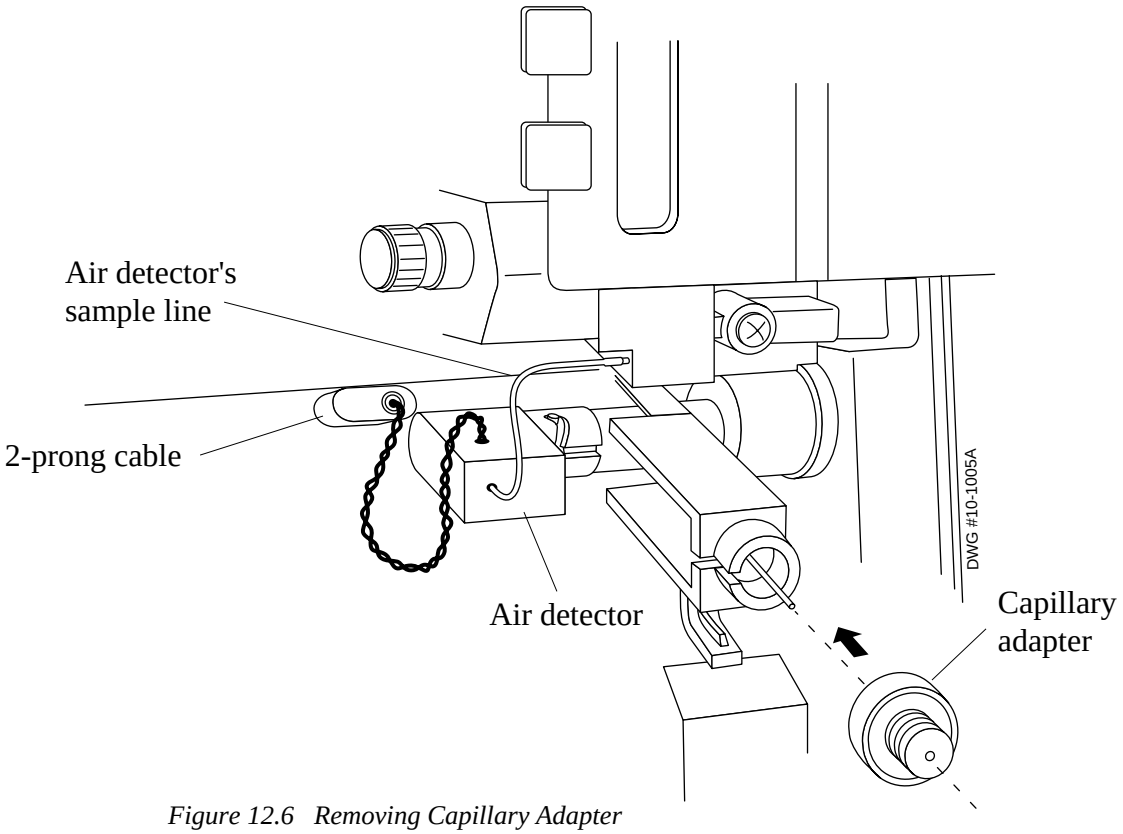


Figure 12.6 Removing Capillary Adapter

NOTES:

7. Discard the used probe.
8. Place a new probe into the air detector and slide both into the sampler assembly. (See Figure 12.7.)
9. Push the air detector up to lock the probe and air detector into the sampler assembly.

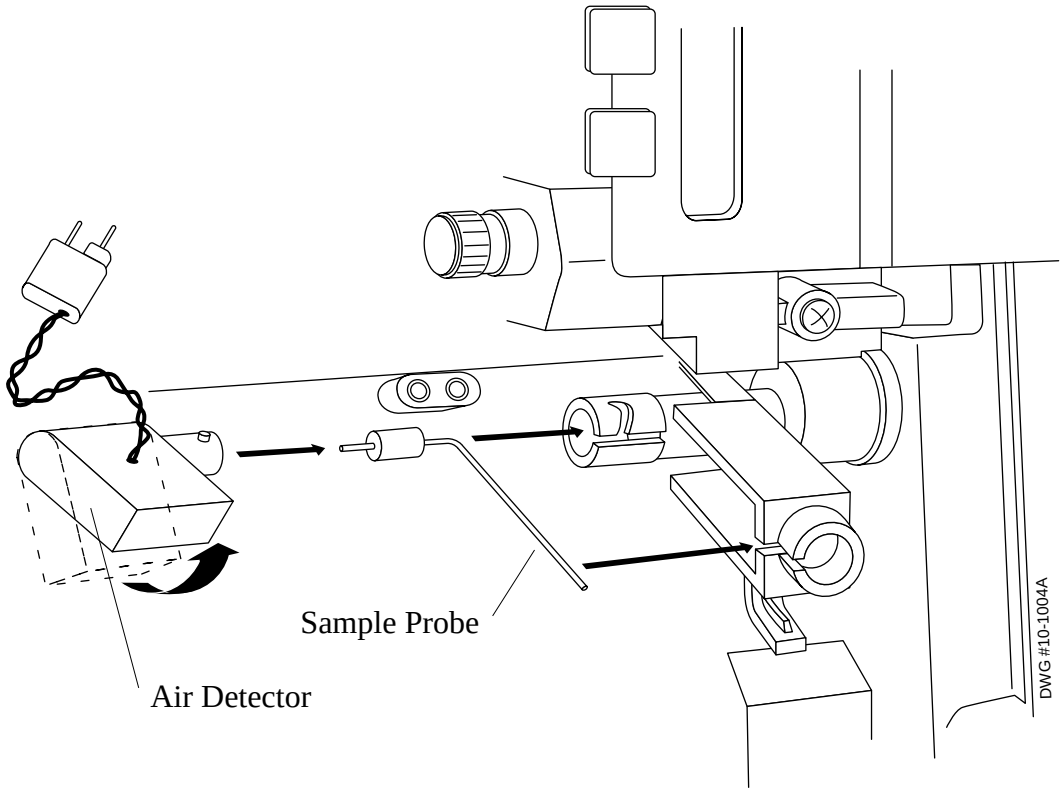


Figure 12.7 Replacing Probe and Air Detector

10. **If changing the probe, do this step; if not skip to next step.** Replace the capillary adapter over the end of the probe. The probe must go through the center of the adapter to work probably.
11. Reconnect the air detector's sample line.
12. Connect the cable back into outlet.
13. Close the door and press the Continue key (soft key).
14. A message displays, Priming Flow Path. Please wait., and a time bar to completion also appears.

NOTES:

13 Setup

13.1 Adapting the Analyzer to Meet Your Requirements

The Stat Profile pHOx Analyzer has many features that can be modified to match the way you operate in your laboratory. To take advantage of these you will need to be familiar with the Set Up Menu.

Choices that you make through setup affect:

- Who can access the setup menu.
- The way patient results are reported.
- Calibration times and Analysis outputs.
- Communications with external devices.

13.1.1 Data Input Display Options

Run an analysis. Attach the printout to the page.

Units
Circle your facility's choice:

Temperature	°F	°C.	
PO_2 /PCO_2	mmHg	kPa	
pH/H+	pH	H+	
Hemoglobin	g/dL	mmol/L	g/L

Do you want to enter Reference ranges? Yes No
Alert ranges? Yes No

If Yes, What are your ranges?

	Reference Ranges Low - High		Alert Ranges Low - High	
pH	_____	_____	_____	_____
PCO_2	_____	_____	_____	_____
PO_2	_____	_____	_____	_____
SO_2%	_____	_____	_____	_____
Hct	_____	_____	_____	_____
Hb	_____	_____	_____	_____

NOTES:

13.1.2 General Operating Options

Will you be using Remote Review?	Yes	No
Will you be connected to a CO-Oximeter?	Yes	No
Do you wish to password control access to the analyzer?	Yes	No
Do you have a laboratory computer or PDM to be interfaced?	Yes	No
If yes, Specify the LIS. _____		

How often do you want the system to do a 2-point calibration?	2hr	4hr	6hr
What type of Analysis mode?	A		B
How do you want the Analysis Transmit mode?	Manual		Auto
Do you want to transmit Analysis Diagnostic Data?	Yes		No
How do you want the Analysis Print mode?	Manual		Auto
Do you want to Print Diagnostic Data?	Yes		No

Do you want to transmit Calibration Diagnostic Data?	Yes	No
Do you want to Print Calibration Diagnostic Data?	Yes	No
*Do you want to transmit Calibration drift data?	Yes	No
*Do you want to print the Calibration drift data?	Yes	No

NOTE: *California requires Calibration Drift information.*

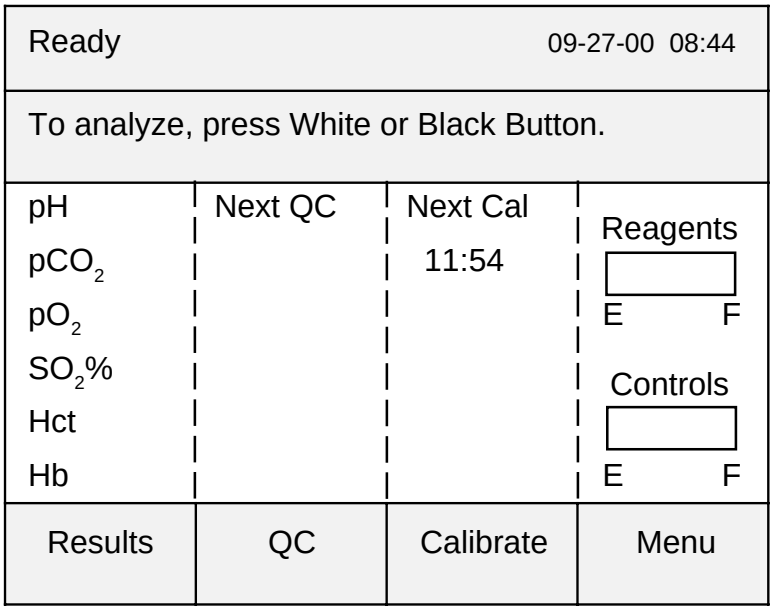
13.2 Inputting Selections

Now that you have decided how you want the printout to look and how the pHOx is to run, use the Setup Menu to adapt the analyzer to your requirements.
A password, which safeguards the setup parameters, is required to enter the Setup Menu.

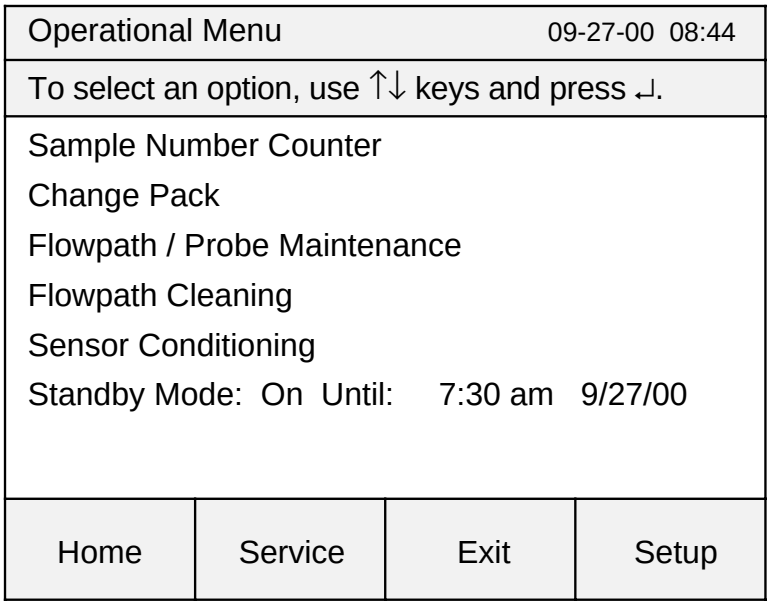
NOTES:

13.3 Setup Menu Checklist

1. Press the Menu (soft key) from the Ready (Home) screen.



2. Press the Setup (soft key) from the Operational Menu.



3. Enter a Password when the System Password pop-up screen appears.

NOTE: *The analyzer is factory set with 0 as the default password.*

4. Press OK (soft key). The Setup Menu will appear.

NOTES:

Setup Menu			
Use ↑↓ to select, press ↵ to change.			
Results Configuration Menu			
Operation Configuration Menu			
Communications Menu			
Printer			Installed
Passwords			
Operator Passwords			
Language			English
Home		Exit	

13.3.1 Results Configuration Menu Checklist

1. Use the arrow key to highlight Results Configuration Menu.
2. Press Enter.

Results Configuration			
Use ↑↓ to select, press ↵ to change.			
Reference & Alert Limits Setup			
Electrode Offsets Setup			
Results Units Setup			
Results Suppression			
Remote Review: ON/OFF			
Patient Name: ON/OFF			
Mandatory Patient ID: ON/OFF			
Home		Exit	

NOTES:

13.3.1.1 Reference & Alert Limits Setup Checklist

1. If already in the Results Configuration Menu, use the arrow keys to highlight Reference & Alert Limits Setup.
2. Press Enter.

Reference & Alert Limits Setup			
Use ↑↓ to select, press ↵ to change.			
	low-Ref-High		low-Alert-High
pH	6.5 - 8.0		6.5 - 8.0
pCO2	3.0 - 200.0		3.0 - 200.0
pO2	0.0 - 800.0		0.0 - 800.0
SO2%	30.0 - 99.9		30.0 - 99.9
Hct	12 - 70		12 - 70
Hb	40 - 240		40 - 240
Home		Exit	

3. Highlight the position to input the low or high reference or alert value by using the arrow keys.
4. Enter the numeric value for all analytes.
5. Press Enter
6. Press Exit (soft key) to go back one page to the Results Configuration Menu, to continue with the Setup Menu, or press Home (soft key) to return to the Ready screen and cancel out of the Setup Menu.

NOTES:

13.3.1.2Electrode Offsets Setup Checklist

1. If already in the Results Configuration Menu, use the arrow down key to highlight Electrode Offsets Setup.
2. Press Enter.
3. Use the arrow keys to highlight the position to enter the slope and/or offset.

Lower and Upper Limits

	Slope	Offset
pH	N/A	-0.1 to 0.1
PCO_2	0.80 to 1.20	-10.0 to 10.0
PO_2	0.90 to 1.0	-20.0 to 20.0
SO_2%	0.90 to 1.0	N/A
Hct	0.80 to 1.20	-10.0 to 10.0
Hgb	0.9 to 1.0	-2.0 to 2.0

Electrode Offsets Setup			
Use ↑↓ to select, press ↵ to change.			
Electrode	Slope	Offset	
pH		0.000	
pCO2	1.00	0.0	
pO2	1.00	0.0	
SO2%	1.00		
Hct	1.00	0	
Hb	1.00	0	
Home		Exit	

4. Enter the numeric value.
5. Press Enter.
6. Continue to the next analyte using the arrow keys until all values are entered.
7. Press Exit (soft key) to go back one page to the Results Configuration Menu or press Home (soft key) to return to the Ready screen and cancel out of the Setup Menu.

NOTES:

13.3.1.3Results Units Setup Checklist

1. If already in the Results Configuration Menu, use the down arrow key to highlight Results Units Setup.
2. Press Enter.

Results Units Setup			
Use ↑↓ to select, press ↵ to change.			
Temp	C		
Blood Gas	mmHg		
pH/H+	pH		
Hb	g/dL		
Home		Exit	

3. Use the arrow key to highlight the Temp option.
4. Press Enter to toggle between the choices: °F or °C.
5. After making the Temp selection use the down arrow key to highlight the Blood Gas option.
6. Press Enter to toggle between the choices: mmHg or KPa.
7. After making the blood gas selection, use the down arrow key to highlight the pH/H+ option.
8. Press Enter to toggle between the choices: pH or H^+.
9. After making the pH/H+ selection, use the down arrow key to highlight the Hb option.
10. Press Enter. A pop-up screen appears with choices: g/dL mmol/L g/L.
11. Use the right or left arrow key to select the unit.
12. Press Enter.
13. Press Exit (soft key) when finished to go back a page to the Results Configuration Menu or press Home (soft key) to return to the Ready screen and exit out of Setup Menu.
14. Press Exit (soft key) from the Results Configuration screen to go back to the Setup Menu.

NOTES:

13.3.1.4Results Suppression Checklist

In the Results Configuration screen, test results can be suppressed: these tests will not be displayed, printed, or transmitted. The suppressed results will only affect analysis results: it will still calibrate. Measured tests that depend on the results from a suppressed test will not be displayed. A dependency error is displayed.
Calculated parameters that depend on suppressed results are not calculated.

Results Suppression			
Use ↑↓ to select, press ↵ to change.			
pH pCO_2 pO_2 SO_2% Hct Hb	Suppressed Suppressed 		
Home		Exit	

Suppress results as follows:

1. In the Results Configuration screen, scroll down to Results Suppression.
2. Press the Enter key to get a pop-up screen of the tests.
3. Scroll to the test that you want to suppress then press the Enter key.
4. Scroll to the next test or exit from screen.
5. On the Home screen, the suppressed test will have a strike through the test; no results will be reported on this test.

NOTES:

13.3.1.5Remote Review

When the pHOx Analyzer is connected to a PDM (Patient Data Management system) and the passwords are turned on, the customer has the option of having the results review by a qualified person in another area. Turn on Remote Review as follows.

1. If already in the Results Configuration Menu, use the down arrow key to highlight Remote Review.
2. Press Enter to toggle between the choices: OFF or ON.
3. To continue to the next menu selection, use the down arrow key to highlight the next selection on the Results Configuration screen; or, if finished, press Exit (soft key) to go back to the Setup Menu; or press Home (soft key) to return to the Ready screen.

13.3.1.6Patient Name

The Name of a Patient can be entered on the Information screen using alpha keys from an external key board when the patient name menu is turned on.

1. If already in the Results Configuration Menu, use the down arrow key to highlight Patient Name.
2. Press Enter to toggle between the choices: OFF or ON.
3. To continue to the next menu selection, use the down arrow key to highlight the next selection on the Results Configuration screen; or, if finished, press the Exit (soft key) to go back to the Setup Menu; or press Home (soft key) to return to the Ready screen.

13.3.1.7Mandatory Patient ID

1. If already in the Results Configuration Menu, use the down arrow key to highlight Mandatory Patient ID.
2. Press Enter to toggle between the choices: OFF or ON.
3. To continue to the next menu selection, use the down arrow key to highlight the next selection on the Results Configuration screen; or, if finished, press the Exit (soft key) to go back to the Setup Menu; or press Home (soft key) to return to the Ready screen.

NOTES:

13.3.2 Operation Configuration Checklist

1. If already in the Setup Menu, use the down arrow key to highlight Operation Configuration.
2. Press Enter.

Setup Menu			
Use ↑↓ to select, press ↵ to change.			
Results Configuration Menu Operation Configuration Menu Communications Menu Printer Installed System Password Language English			
Home		Exit	

Operation Configuration Menu			
Use ↑↓ to select, press ↵ to change.			
Analysis Configuration Calibration Configuration System Configuration Analysis Mode: A Hb Type: Hb Measured Stat Mode: OFF			
Home		Exit	

3. Use the arrow key to highlight Analysis Configuration.
4. Press Enter.

NOTES:

13.3.2.1 Analysis Configuration Checklist

1. Use the arrow key to highlight Analysis Configuration.
2. Press Enter.

Analysis Configuration	
Use ↑↓ to select, press ↵ to change.	
Analysis Transmit Mode	Auto
Transmit Diagnostic Data	OFF
Analysis Print Mode	Auto
Print Diagnostic Data	OFF
CO-Ox Data Merge	Patient ID
Set Analyzer ID Number:	1

Home		Exit	

3. Use the arrow key to highlight Analysis Transmit Mode.
4. Press Enter to toggle between the choices: Auto or Manual.
5. Use the down arrow key to highlight Transmit Diagnostic Data.
6. Press Enter to toggle between the choices: Off or On.
7. Use the down arrow key to highlight the Analysis Print Mode option.
8. Press Enter to toggle between the choices: Auto or Manual.
9. Use the down arrow key to highlight the Print Diagnostic Data option.
10. Press Enter to toggle between the choices: Off or On.
11. Use the down arrow key to highlight the CO-Ox data merge position.
12. Press Enter to toggle between the choices: Accession Nbr or Patient ID.
13. Use the down arrow key to highlight the Set Analyzer ID Number position.
14. Enter a numeric number (0 to 99 digits) to identify this analyzer. Press Enter.
15. Press Exit (soft key) to go back to the Operation Configuration Menu or press Home (soft key) to return to the Ready screen and exit the Setup Menu.

NOTES:

13.3.2.2 Calibration Configuration Checklist

1. If already in the Operation Configuration Menu, use the down arrow key to highlight Calibration Configuration.
2. Press Enter.

Calibration Configuration	
Use ↑↓ to select, press ↵ to change.	
Set 1 Point Calibration Frequency	30 min.
Set 2 Point Calibration Frequency	6 hr.
Transmit Diagnostic Data	OFF
Print Diagnostic Data	OFF
Transmit Drift Data	OFF
Print Drift Data	OFF

Home		Exit	

3. Use the arrow key to highlight Set 1 Point Calibration Frequency option.
4. Press Enter to toggle between the choices. 30 minutes or 45 minutes
5. Use the down arrow key to highlight Set 2 point Calibration Frequency option.
6. Press Enter.
7. A pop-up screen appears with choices: 2hr, 4hr, 6hr. Use the left or right arrow key to make a selection.
8. Press Enter
9. Use the down arrow key to highlight Transmit Diagnostic Data option.
10. Press Enter to toggle between the choices: On or Off.
11. Use the down arrow key to highlight Print Diagnostic Data option.
12. Press Enter to toggle between the choices: On or Off.
13. Use the down arrow key to highlight Transmit Drift option.
14. Press Enter to toggle between the choices: On or Off.
15. Use the down arrow key to highlight Print Drift option.
16. Press Enter to toggle between the choices: On or Off.
17. Press Exit (soft key) to go back a page to Operation Configuration Menu or press Home (soft key) to return to the Ready screen and exit the Setup Menu.

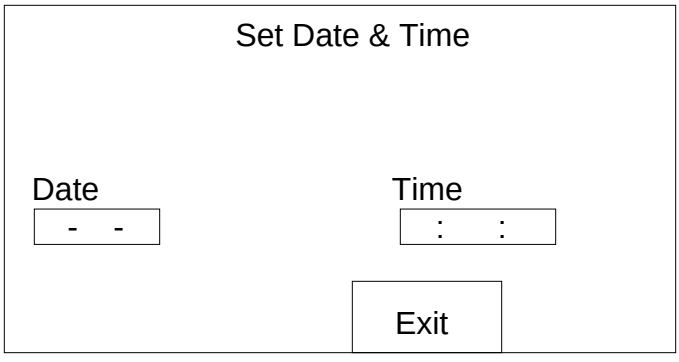
NOTES:

13.3.2.3 System Configuration Checklist

1. If already in the Operation Configuration Menu, use the down arrow key to highlight System Configuration.
2. Press Enter.

System Configuration			
Use ↑↓ to select, press ↵ to change.			
Set Date Format	MM/DD/YY		
Set Time Mode	24 hr. mode		
Date & Time	Set		
Measured Barometric Pressure	760 mmHg		
Corrected Barometric Pressure	mmHg		
Set Default Hb used in Calculations	14.3 g/dL		
Set Tone frequency (100-5000 Hz)	1500 Hz		
Home		Exit	

3. Use the arrow key to highlight Set Date Format option.
4. Press Enter.
5. A pop-up screen will appear with format choices:
   DD/MM/YY
   MM/DD/YY
   YY/MM/DD
6. Use the up or down arrow key to highlight your date format choice
7. Press Enter.
8. Use the down arrow key to highlight Set Time Mode option.
9. Press Enter to toggle between the choices: 12hr mode or 24hr mode.
10. Use the down arrow key to highlight Date & Time option.
11. Press Enter.



NOTES:

12. Highlight Date.
13. Press Enter.
14. Enter the Date in the proper format using the numeric keys.
15. Press Enter.
16. Use the left or right arrow key to highlight Time option.
17. Press Enter.
18. Enter the time in the proper format using the numeric keys.
19. Press Enter..
20. Use the left or right arrow key to highlight Corrected Barometric Pressure option.
21. Press Enter.
22. Use the numeric keys to enter a numeric value between 400 to 800 for the Barometric Pressure.
23. Press Enter.
24. Use the left or right arrow key to highlight Set Default Hb used in Calculations option.
25. Press Enter.
26. Use the numeric keys to enter a numeric value.
27. Press Enter.
28. Use the left or right arrow key to highlight Set Tone Frequency option.
29. Press Enter.
30. Use the numeric keys to enter a numeric value between 100 to 5000.
31. Press Enter.
32. Press Exit (soft key) to go back to the Operation Configuration Menu or press Home (soft key) to return to the Ready screen.

NOTES:

13.3.2.4Analysis Mode Checklist

1. If already in the Operation Configuration Menu, use the down arrow key to highlight Analysis Mode.
2. Press Enter to toggle between the choices: A or B.

Mode A: One point fluid calibration is performed with each Gas Cal I (30-45 min. intervals)
Best for medium-high volume customer

Mode B: 1-point fluid calibration & Gas Cal is performed with EACH analysis
Best for Low volume customers
No separate Gas Cal I done

13.3.2.5 Hb Type Checklist

1. If already on the Operation Configuration Menu, use the down arrow key to highlight Hb Type.
2. Press Enter to toggle between the choices: Hb Calculated or Hb Measured.
3. Press Exit (soft key) to go back a page to the Setup Menu or press Home (soft key) to go to the Ready screen and exit the Setup Menu.

13.3.2.6 Stat Mode

1. If already on the Operation Configuration Menu, use the down arrow key to highlight Stat Mode.
2. Press Enter to toggle between the choices: OFF or On.
3. Press Exit (soft key) to go back a page to the Setup Menu or press Home (soft key) to go to the Ready screen and exit the Setup Menu.

NOTES:

13.3.3 Communication Menu Checklist

1. If already on the Setup Menu, use the down arrow key to highlight Communications Menu.
2. Press Enter.

Setup Menu			
Use ↑↓ to select, press ↵ to change.			
Results Configuration Menu			
Operation Configuration Menu			
Communications Menu			
Printer			Installed
Passwords			
Operator Passwords			
Language			English
Home		Exit	

Communications					
Use ↑↓ to select, press ↵ to change.					
Port	Baud	Data Bits		Stop	Parity
Computer(COM2)	OFF	8		1	none
External Keyboard: NO					
CO-Ox Attached: No					
Note: The CO-Oximeter and Bar Code Reader ports do not have configuration settings.					
Home		Exit			

3. Use the arrow keys to highlight Baud under the appropriate Port (ASTM or Remote)
4. Press Enter.
5. A pop-up screen with choices appears:

   4800
   9600
   19200
   OFF

NOTES:

6. Use the up or down arrow key to highlight baud.
7. Press Enter.
8. Use the right arrow key to highlight Data Bits.
9. Press Enter to toggle between the choices: 7 or 8.
10. Use the right arrow key to highlight Stop.
11. Press Enter to toggle between the choices. 1 or 2
12. Use the right arrow key to highlight Parity.
13. Press Enter.
14. A pop-up screen will appear with choices:
    None
    Even
    Odd
15. Use the down arrow key to highlight the parity.
16. Press Enter.
17. Use the down arrow key to highlight CO-Oximeter Attached option.
18. Press Enter to toggle between the choices. Yes or No
19. After the selections have been made press Exit (soft key) to go back a page to the Setup Menu or press Home (soft key) to return to the Ready screen and exit Setup Menu.

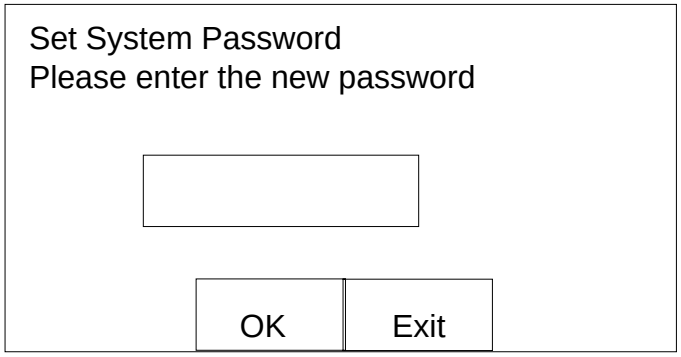
13.3.4 Printer Checklist

1. If already in the Setup Menu, use the down arrow key to highlight Printer.
2. Press Enter to toggle between the choices: Installed or Not Installed.

NOTES:

13.3.5 System Password Checklist

1. If already in the Setup Menu, use the down arrow key to highlight Passwords. Press Enter.
2. A pop-up screen appears. Select System Password.
3. Use the numeric keys to enter a new system password.
4. Press the Enter key, the screen will revert back to the Setup Menu.
5. To Cancel entering a new password press Exit (soft key), the screen will revert back to the Setup Menu.



13.3.6 Operator Password Checklist

The Operator Passwords allows you the ability to enable and to enter 200 unique passwords with privilege levels. When enabled, password entry will be required whenever any of the home screen soft keys, syringe key, or capillary key are pressed. Entry into any one of the protected areas depends on the privilege level assigned to the operator of the analyzer.

There are 3 privilege levels: Privilege Level 1 is the most privileged operator and Privilege level 3 is the default level.

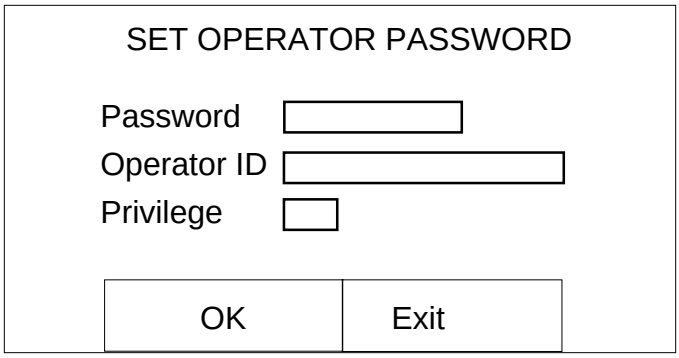
- Privilege Level 1 operators have access to all areas of the analyzer except those protected by the existing System Password. Level 1 operators do not require PDM review and may override this feature. Level 1 operators can override QC lockout.
- Privilege Level 2 operators have access to all areas of the analyzer except those protected by the existing System Password. Level 2 operators will require PDM review, but may override this feature. Level 2 operators cannot override QC lockout.

NOTES:

- Privilege Level 3 operators have access to analysis only. Level 3 operators will require PDM review before the results are released. Level 3 operators cannot override QC lockout.

Set up Operator Passwords as follows:

1. Press Menu on the Ready screen to display the Operational Menu screen.
2. Press Setup to display the Setup Menu screen.
3. A pop-up Password screen appears. Enter the default password, 0. This is the password until one is officially entered.
3. Scroll down with the arrow keys to the Password option and press Enter. A pop-up screen appears: select Operator Password.
4. Key in a password number, (up to 4 numeric characters), an operator ID, and a Privilege level (3 levels) and press OK.
5. To enable Operator Passwords, scroll down to Operator Passwords then press the Enter key: Off will turn to On.
6. Proceed to the next setup option or return to the Operational Menu.



13.3.7 Language Checklist

1. If already in the Setup Menu, use the down arrow key to highlight Language.
2. Press Enter. A pop-up screen will appear with choices: Chinese, English, French, German, Italian, Japanese, Spanish.
3. Use the arrow key to make a selection.
4. Press Enter to select the language.
5. Press Home (soft key) or Exit (soft key) twice when finished to return to the Ready screen.

NOTES:

NOTES:

14 QC Setup

The QC setup screens allow the set up of external or internal controls for data collection.
Both the internal and external controls can be programmed for analysis 3 times daily, as long as the Automatic QC option is turned ON. When QC Lockout is turned ON and QC is due, the analyzer becomes Not Ready. A QC must be performed before an analysis can be run.
When you change a lot number of control, all the previous data for the previous Lot Number will be erased. Remember to print out this data before changing Lot Numbers.

14.1 QC Setup Checklist

1. From the Ready screen, press the QC (soft key) to access the QC Setup screen.

Ready		09-27-00 08:44	
To analyze, press White or Black Button.			
pH pCO_2 pO_2 SO_2% Hct Hb	Next QC	Next Cal 11:54	Reagents E F Controls E F
Results	QC	Calibrate	Menu

NOTES:

2. Once in the Quality Control Screen, use the down arrow key to highlight Setup QC.
3. Press Enter.

Quality Control (QC)			
To select an option, use ↑↓ keys and press ↵.			
Analyze QC View or Print QC Data Setup QC Automatic QC Analysis OFF			
Home		Exit	

4. A System Password pop-up screen appears.
5. Enter the System Password using the numeric keys.

NOTE: *The analyzer is factory set with 0 as the default password.*

6. Press OK (soft key). The QC Setup screen will then appear.

QC Setup External 1			
Use ↑↓ to select, press ↵ to change.			
Control Lot Expiration Date: Daily Analysis Times: QC Lockout OFF Set Ranges			
Home	Next Control	Exit	Previous Control

NOTES:

14.1.1 Control Lot Checklist

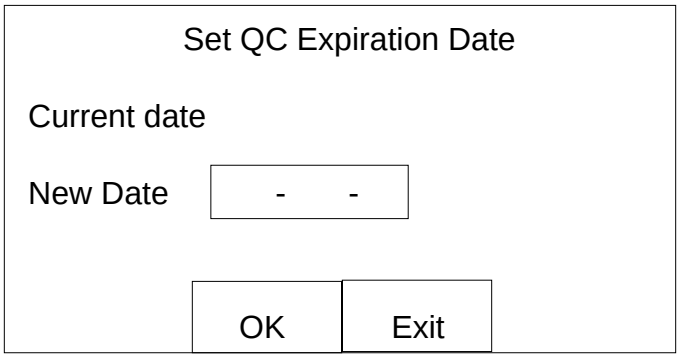
NOTE: *The lot number for the Auto-cartridge QC (internal controls) is automatically entered.*

1. Once on the QC Setup screen, verify what control screen (External 1, External 2, External 3, External 4, External 5, Internal 1, Internal 2, Internal 3) you are viewing by looking at the top of the screen.
2. Press Next Control (soft key) to find the correct control.
3. Highlight Control Lot using the arrow keys.
4. Press Enter.
5. Enter the Lot Number using the numeric keys.
6. Press Enter.

14.1.2 Expiration Date Checklist

NOTE: *The expiration date for the Auto-cartridge QC (internal controls) is automatically entered.*

1. If already on the QC Setup Screen under the correct control, highlight Expiration Date using the down arrow key.
2. Press Enter.
3. A pop-up screen appears. Enter the expiration Date using the numeric keys.
4. Press OK (soft key) after entering the expiration date. To cancel entering Expiration date press Exit (soft key).

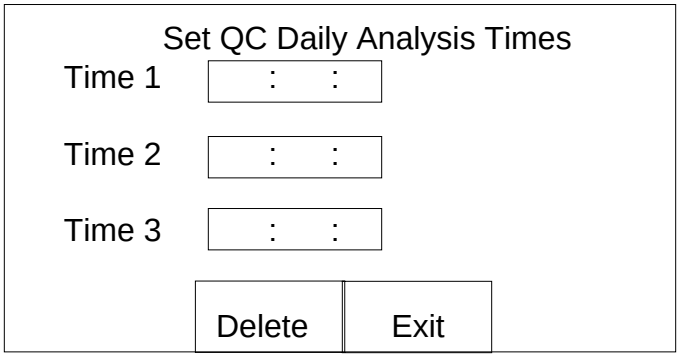


NOTES:

14.1.3 Daily Analysis Time Checklist

To set running controls at specific times.

1. If already on the QC Setup screen under the correct control, use the down arrow key to highlight Daily Analysis Times.
2. Press Enter.
3. A pop-up screen appears to set the times.



4. Press Enter on Time 1.
5. Enter the Time using the numeric keys.
6. Press Enter.
7. If another QC analysis time is wanted, use the down arrow key to highlight Time 2.
8. Press Enter.
9. Enter the Time using the numeric keys.
10. Press Enter.
11. If a third time is wanted, use the down arrow key to highlight Time 3.
12. Press Enter.
13. Enter the Time using the numeric keys.

NOTE: *To Delete a Time highlight the Time and press Delete (soft key).*

14. Press Exit (soft key) when finished entering in times to page back to the QC Setup screen.

NOTES:

14.1.4 QC Lockout Checklist

1. If already on the QC Setup screen under the correct control, use the down arrow key to highlight QC Lockout.
2. Press Enter to toggle between the choices.: ON or OFF.

NOTE: *When turning on the QC Lockout, at least one QC Daily Analysis time must be programmed into the system.*

QC Setup External 1			
Use ↑↓ to select, press ↵ to change.			
Control Lot Expiration Date: Daily Analysis Times: QC Lockout OFF Set Ranges			
Home	Next Control	Exit	Previous Control

14.1.5 Set Ranges Checklist

1. If already on the QC Setup screen under the correct control, use the down arrow key to highlight Set Ranges.
2. Press Enter.

QC View Ranges External 1			
To change ranges press edit button.			
Test	Expected Range		Units
pH	6.5 -	8.0	
pCO2	3.0 -	200.0	mmHg
pO2	0 -	800	mmHg
SO2%	30 -	99.9	
Hct	12 -	70	%
Hb	40 -	240	g/dL
Home	Edit	Exit	Print

NOTES:

3. Press Edit (soft key) to enter values in for each test.
4. Use the arrow keys to highlight the position for each test in which a range is to be entered.
5. Use the numeric keys to enter the number.
   The expected range for each analyte must be between the following ranges:

pH	6.5 - 8.0
PCO_2	3.0 - 200.0
PO_2	0 - 800
SO_2%	30 - 99.9
Hct	12 - 70
Hb	40 - 240

   or a pop-up screen will appear stating the entered data is not within the allowable range.

6. To remove an entered range, highlight the analyte range to be removed and press Disable (soft key).

QC View Ranges External 1			
To change ranges press edit button.			
Test	Expected Range		Units
pH	6.5	- 8.0	
pCO2	3.0	- 200.0	mmHg
pO2	0	- 800	mmHg
SO2%	30	- 99.9	
Hct	12	- 70	%
Hb	---	- ---	g/dL
Home	Disable	Exit	Print

7. Press Exit (soft key) when finished to page back to the QC Setup screen in order to enter another control, otherwise press Home (soft key) to return to the Ready screen.
8. To set ranges for another control press Next Control (soft key) on the QC Setup screen and follow the steps listed on the previous pages to enter the appropriate information.

NOTES:

15 Troubleshooting Lab

15.1 Troubleshooting Exercises

Write in the space provided on the following pages:

1. What are the **SYMPTOMS** that you observed? (Error codes, slopes, flow numbers, leakage, etc.)

2. **HOW** did you find the problem? (Flow test, observation, etc.)

3. What was the **CAUSE** of the problem, and what did you do to resolve it?

4. Based on the problem that you found, explain **WHY** we see these errors.

Remember:

- **CHECK** with the instructor to make sure that you have found the problem.

NOTES:

Problem #1

Symptom(s)

Troubleshooting Approach Used

Cause and Solution

Explanation of Errors

Problem #2

Symptom(s)

Troubleshooting Approach Used

Cause and Solution

Explanation of Errors

NOTES:

Problem #3

Symptom(s)

_____
_____
_____

Troubleshooting Approach Used

_____
_____
_____

Cause and Solution

_____
_____
_____

Explanation of Errors

_____
_____
_____

Problem #4

Symptom(s)

_____
_____
_____

Troubleshooting Approach Used

_____
_____
_____

Cause and Solution

_____
_____
_____

Explanation of Errors

_____
_____
_____

NOTES:

Problem #5

Symptom(s)

Troubleshooting Approach Used

Cause and Solution

Explanation of Errors

Problem #6

Symptom(s)

Troubleshooting Approach Used

Cause and Solution

Explanation of Errors

16 Examination/Evaluation

16.1 Certificate and C.E.U. Credits (In-Service Attendees Only)

Each person who attended the in-service and who would like to receive a certificate of attendance should complete an individual copy of the enclosed examination and evaluation form. Please make sure that you have included your name and mailing address and that these are legible.

Nova Biomedical is approved as a provider of continuing education programs in the clinical laboratory sciences by the ASCLS P.A.C.E. program and by the Board of Clinical Laboratory Personnel for those licensed in the state of Florida. To receive your C.E.U. credit, please submit your examination and evaluation within 2 weeks of your participation in training. Those exams with a post mark more than 2 weeks from last day of training cannot be issued C.E.U. credits. This deadline is necessary due to the registration deadline enforced by our accreditation agency. Nova will submit the number of training contact hours to the appropriate professional organization. In order to process your request we will need to know:

- Your name
- Your Social Security Number
- Your institution name
- Your professional affiliation (RT, MT, RN, etc.)
- Your registration or license number, if applicable.
- The number of contact hours (provided by the NOVA field training specialist)

Mail these to:

Training Coordinator
Nova Biomedical
200 Prospect Street
Waltham, MA 02454-9141

Please allow several weeks for your certificate to be prepared and returned to you.
If you have questions on C.E.U. credits or certificates, contact Nova's training coordinator at (800) 545-NOVA.

Training Examination

Name _____ Date(s) of Training_____

Facility Name _____

Address _____

_____

Circle one: Home or Work address.

General Instructions

You may use your notes, the instrument, or any of the manuals to answer the exam questions. The exam is not intended to be a group exercise.

Fluidics

1. True or False _____ Reference solution is monitored (sensed) by the air detectors.

Operation

2. True or False _____Stat Profile pHOx controls should be stored at 37° C for approximately 24 hours prior to analysis.

3. True or False _____ If the Stat Profile pHOx's internal barometer becomes inoperative, no blood gas specimens can be analyzed.

4. When would you use Stat Profile preheater cleaning agent?

   A. Daily
   B. Weekly
   C. Monthly
   D. As needed

5. An ampule of control should be analyzed within ____ of opening.

   A. 10 minutes
   B. 5 minutes
   C. 30 Minutes
   D. 30 seconds

6. True or False _____ A sample with a lithium heparin concentration of no more than 60 IU/mL is acceptable for the Stat Profile pHOx.

7. For the following, assume that an ampule of normal level control has been left open for 5 minutes prior to analysis. What will happen to the values listed in the table below? Fill in the blank with the appropriate letter.

   A. Begin to increase B. Begin to decrease C. Be unaffected

   The PO_2 value will... ___
   The PCO_2 value will... ___
   The pH value will... ___

8. True or False ___ If the sodium electrode is uncalibrated, the Hct value will not be printed.

9. True or False ___SO_2 requires Hct and PO_2 to be calibrated.

10. True or False ___ Hgb requires Hct and SO_2 for reporting.

Maintenance

11. True or False ____ A prime cycle using distilled water is necessary when replacing a reagent pack.

12. Circle the sensor(s) that is/are subject to the described maintenance procedure.

Condition with pH conditioning solution.	pH	PCO_2	PO_2	Na^+	SO_2	Reference
Replace membrane cap.	pH	PCO_2	PO_2	Na^+	SO_2	Reference
Flush with water.	pH	PCO_2	PO_2	Na^+	SO_2	Reference
Polish sensor.	pH	PCO_2	PO_2	Na^+	SO_2	Reference
Clean with preheater cleaning solution.	pH	PCO_2	PO_2	Na^+	SO_2	Reference
No maintenance required.	pH	PCO_2	PO_2	Na^+	SO_2	Reference

Diagnostics/Troubleshooting

13. True or False ___ The pH sensor normally has a negative (-) slope number.

14. Which of the following can affect PO_2 and PCO_2 values on patient samples?

    A. Barometric pressure
    B. Patient temperature
    C. Neither A or B
    D. Both A and B

15. The following are symptoms of flow problems: Flow Too Slow, Insufficient Sample. What are 3 possible causes?

_____
_____
_____

Training Evaluation

Your Name _____

Account Name _____ Contact/Phone # _____

Analyzer Model _____ Date(s) of Installation _____

Trainer's Name _____

YOUR INPUT IS CRITICAL TO US. You've just attended a Nova product training seminar. Please take the time to answer our questions and add your own thoughts. Check one box for each question and add your comments. If you need more space, please feel free to use the back of this form.

	Not at All				Very Much
1. Did the course contain all the information you need? (If not, please explain below.)	1	2	3	4	5
2. Did you understand what was being presented?	1	2	3	4	5
3. Were your questions answered effectively?	1	2	3	4	5
4, Do you feel that you had enough time to learn? (If not, please explain below.)	1	2	3	4	5
5. Do you feel confident that you can use what you learned in your daily work? (If not, please explain below.)	1	2	3	4	5
6. Was the training session free of distractions?	1	2	3	4	5

	Poor	Fair	Ave.	Good	Exc.
7. The instructor's knowledge of the analyzer was.....	1	2	3	4	5
8. The instructor's ability to present information in a way you could understand was.....	1	2	3	4	5

Additional Suggestions or Comments:

NOTES:

A.1 Technical Assistance

A.1.1 Telephone Technical Support (Hot Line) ☎

Telephone technical support is available on a 24 hour basis at no charge to all Nova analyzer owners including the PDM.

How to reach us :

Monday through Friday **8:00 AM to 6:00 PM EST,** our Waltham facility is in operation. Weekends, nights **(6:00 PM to 8:00 AM EST),** and U.S. federal holidays when the Waltham facility is closed, calls for technical assistance are routed from our answering service to Nova's on-call personnel.

In North America and Puerto Rico call : **(800) 545-NOVA or (781) 894-0800.**
To fax data, etc.: **(781) 894-0585.**
Outside North America, contact your local distributor.

To help us locate your records (and you!), please provide our operators with the following information:

- Your name.
- Your facility name and location (i.e.: I.C.U. lab, O.R. lab, satellite lab, etc.).
- The analyzer model and serial number (Stat Profile pHOx, SN QCC123456).
- The correct phone number and extension or pager number.

NOTES:

A.1.2 Field Service Support

Nova can provide a field service representative necessary to carry out a repair at your location. Field service may fall into one of the following categories:

Warranty Service

The first 12 months after installation is generally considered the analyzer warranty period. Travel, labor, and nonconsumable parts costs for reasonable on-site service by a Nova service representative are covered by the analyzer warranty.
Warranty service is performed Monday through Friday between the hours of 9:00 AM and 5:00 PM local time. Weekend service is available for an additional hourly charge. All service requests are dispatched from the Waltham facility. Contact the Nova Technical Services for details.

Service Agreements

Nova offers a range of service agreements and reagent rental plans to protect your analyzer investment. We provide options for coverage of nonconsumable parts, travel, and labor costs. We can arrange for training updates at your location as part of your service agreement. A summary of these options is included with your information packet. Please contact the Service Agreement Coordinator at (800) 458-5813 Ext. 470 for details.

Billable Service

This category includes on-site service after warranty when no service agreement is in effect. Parts, labor, and travel expenses are billed to a bona-fide purchase order number. Contact the Nova Technical Services for current rates and policies.

NOTES:

A.2 Ordering Parts

In the U.S. and Puerto Rico

Monday through Friday 8:00 AM to 7:30 PM EST our toll free U.S. Order Services numbers are

(800) 822-0911 or (800) 458-5813

Fax numbers: **(800) 316-1178 or (781) 893-6998**

In Canada

Order through Nova Biomedical Ltd. of Missasauga, Ontario, at **(800) 263-5999 or (905) 567-7700.**

Outside North America

Contact your local distributor.

A.2.1 Recommended Spare Parts

One of the best assurances against downtime is an adequate supply of spare parts and frequently used consumable items. The way that the analyzer is used and your facility's ordering practices will affect your usage of parts and supplies. Refer to the list at the end of **Appendix A** in the **Reference Manual** to help you build an appropriate inventory. Ask your service representative if you need more help with this.

NOTES:

A.3 Warranty Replacements

Most consumable parts are covered by a warranty. Check the **Reference Manual** or item packaging for details. Should you have a part that does not meet its warranty life, we will gladly replace it. To do this we need to know the lot number of the item; the dates of installation and removal; and the reason for removal.

A.4 Emergency (After Hours) Parts Shipments

Some parts are available on an emergency basis on weekends and holidays.

A.5 Reaching your Nova Sales Representative

Nova's Inside Sales Department, located in Waltham, can help you with most sales questions and issues. We check in with our customers from time to time, but we know that occasionally you need to reach someone right away who can help with a special need. To reach your inside sales representative, call: 1 (800) 458-5813 or (781) 894-0800. In addition, all of Nova's field sales representatives can be contacted via a voice mail system or by leaving a message with the Waltham sales office at the above number.

NOTES:

The following list can be detached and located near the telephone for your reference.

– –

nova biomedical Telephone Numbers

Technical Services (Hot Line)		**(800) 545-NOVA or (781) 894-0800**		
Fax		**(781) 894-0585**		
Parts	Nova U.S.	**(800) 822-0911**	or	(781) 894-0800
	Nova U.S. Fax	**(800) 316-1178**		
	Nova Canada	**(800) 263-5999**	or	(905) 567-7700
Sales	Nova U.S.	**(800) 458-5813**	or	(781) 894-0800
	Nova Canada	**(800) 263-5999**	or	(905) 567-7700

Your Analyzer: Stat Profile pHOx (model#) _____

Serial Number _____

Your Fax Number ( ) _____

NOTES:

NOTES:

A.2 Ordering Parts

In the U.S. and Puerto Rico

Monday through Friday 8:00 AM to 7:30 PM EST our toll free U.S. Order Services numbers are

(800) 822-0911 or (800) 458-5813

Fax numbers: **(800) 316-1178 or (781) 893-6998**

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Order through Nova Biomedical Ltd. of Missasauga, Ontario, at **(800) 263-5999 or (905) 567-7700.**

Outside North America

Contact your local distributor.

A.2.1 Recommended Spare Parts

One of the best assurances against downtime is an adequate supply of spare parts and frequently used consumable items. The way that the analyzer is used and your facility's ordering practices will affect your usage of parts and supplies. Refer to the list at the end of **Appendix F** in the **Reference Manual** to help you build an appropriate inventory. Ask your service representative if you need more help with this.

Key Facts (pHOx)

Sample Volume: 40 microliters whole blood (Micro sample)
70 microliters whole blood (Normal sample)

Slope Limits:

pH	9.1 - 11.6
PCO_2	7.9 - 12.6
PO_2	(-15.0) - (-1.6)
SO_2	6.9 - 18.2
Na^+	8.8 - 11.5
Hct	12.0 - 50.0

Measurement Range:

pH	6.50 - 8.00	pH units	H^+ 316.23 - 10.00	nmol/L		
PCO_2	3.0 - 200	mmHg	0.4 - 26.7	kPa		
PO_2	0 - 800	mmHg	0.0 - 106.7	kPa		
SO_2	0.0 - 100	%	0.0 - 1.0			
Hb	4.0 - 24.0	g/dL	40.0 - 240.0	g/L	2.5 - 14.9	mmol/L
Hct	12 - 70	%				

Dependency Rule and Information:

Hct	Requires Na+ calibrated for calibration/results.
PCO_2	Requires pH calibrated for results. (pH is checked on standards to assure bicarb is correct.)
SO_2	Requires Hct and PO_2 calibrated for results (uses calculated SO_2 if measured SO_2 is not available).
Hgb	Requires Hct and SO_2 for reporting. Priority: 1. If linked with the CO-Ox, then CO-Ox Hgb is reported. 2. If no CO-Ox or measured result, calculated result from Hct reading (Hct/3) is reported. 3. If no CO-Ox, no measured, and no Hct, analyzer reports Default Value (Hgb).
$P50$	Measured reported only with PO_2 between 30 and 75 mmHg. P50c is reported when PO_2 is outside above limits. Also $P50$ requires calibrated SO_2% and Hgb/Hct for reporting.
Qsp Qt	Requires 2 separate blood samples for determination: mixed venous and arterial.
RI	Utilizes input or default FIO_2% for calculation.
Calculated Results	Requires calibrated and proper results by measured tests used in calculation.
Suppression (Hgb)	Only Hgb can be suppressed. Your option is to turn Hgb from measured to calculated (one or the other will always appear). Option is done in the Setup Menu.

Running a Syringe Analysis Checklist

NOTES:

☐ Step 1 Check the instrument for readiness.

- Check the display for the Home (Ready) screen.

☐ Step 2 Present sample and begin analysis. (Procedure for syringes)

- Press the White Syringe Button.
- Probe positions for sample aspiration.
  Slide the syringe tip over the extended probe.

> ***CAUTION:*** *Do not allow the sample probe to touch the base of the syringe plunger or the bottom of the sample cup or tube.*

☐ Step 3 Analysis begins.

- Press Aspirate Normal (soft key) to start the sampling. (Or, press Aspirate Micro (soft key) for a smaller sample: 40µL instead of 70µL.)

> ***NOTE:*** *If one of these soft keys is not pressed within 5 minutes of the time the probe extends, the probe automatically starts to move down.*

- When the system signals by an audible alarm, withdraw the sample.
- Press Analyze. The probe moves down.

> ***NOTE:*** *If Analyze is not pressed within 30 seconds after the sample has been aspirated, the probe automatically starts to move down.*

- The analysis begins.
- The Sample information screen is displayed.

Running a Capillary Analysis Checklist

NOTES:

Demo this before trainees attempt it. Skip this section if they do not run capillaries.

☐ Step 1 Check the instrument for readiness.

- Check the display for the Home (Ready) screen.

☐ Step 2 Prepare capillary. (See Section 2.2.4, Capillary Handling Tips)

- Mix sample again by drawing magnet back and forth along the length of the capillary.
- Keeping capillary level, remove cap (or caps) from the ends.
- Remove mixing flea by pulling it out one of the free ends with the magnet.

☐ Step 3 Present sample.

- Press the Black Capillary Button and wait for probe to position.
- Holding one gloved finger over the open end of the capillary, carefully slide the tip of the capillary into the adapter until it just touches the probe.
- The capillary should be in line with probe, not tilted horizontally.

> ***CAUTION: Do not*** *remove your finger from the open end of the capillary yet.*

☐ Step 4 Begin analysis.

- Press Aspirate Normal (soft key) to start the sampling. (Or, press Aspirate Micro (soft key) for a smaller sample: 40µL instead of 70µL.)

> ***NOTE:*** *If one of these soft keys is not pressed within 5 minutes of the time the probe extends, the probe automatically starts to move down.*

- As soon as the pump starts to turn, remove your finger from the open end of the capillary, allowing the sample to be drawn up.

NOTES:

2 Running an Analysis

2.1 Is the Instrument Ready for Analysis?

2.1.1 Home Screen

Check the Home screen for Ready to analyze. The screen displays all analytes with the uncalibrated ones x'd out. Also, the next QC and Calibration times are displayed. A bar graph for the amount of reagents and controls shows the approximate percent remaining.

2.2 Patient Samples — Acceptable Samples/Sample Handling

2.2.1 Acceptable Samples

No urine, CSF, cardioplegia solution, or other body fluids.

The acceptable sample is heparinized whole blood.

Nova instruments are designed for clinical environments to analyze actual patient specimens, not modified blood samples. Specimens removed from the patient, anticoagulated appropriately, and promptly analyzed are the only type of sample where the measurement results will be reliable. Matrix effects/interferences can occur when patient specimens are removed from the body, modified and then measured on a Nova instrument. For example, matrix effects have been seen on Nova analyzers when attempting to analyze samples collected from cell savers used in various surgical procedures. Also, evaluation laboratories run specimens from patients with a wide variety of pathologies and from patients who are being treated with a broad spectrum of therapeutic and pharmacological agents. Despite extensive clinical trials, it is not possible to anticipate every possible combination of transfused blood products, crystalloids, and drugs (or their metabolites) that may be present in a blood sample. As a result, some users have found that their particular patient mix has necessitated making adjustments to maintenance. For example, a high number of cardiopulmonary bypass pump or ECMO (extracorporeal membrane oxygenation) samples result in a need for increased analyzer maintenance. If you are experiencing excessive downtime, you may need to modify your own maintenance schedules. Nova's Clinical Applications Group will assist you in tailoring a maintenance program to meet these needs.

Replacing the Reagent Pack/Capillary Adapter Checklist

NOTES:

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, septum assembly, probe, flow cell, etc.) with care. Gloves and protective clothing are recommended. Dispose of the reagent waste bottle according to your laboratory's biohazardous waste policies.

☐ Step 1 Replace the capillary adapter.

- From the Home (Ready) screen, press Menu.
- Select Change Pack.
- Press Enter. A pop-up screen appears.

Change Reagent Pack
Change Control Pack
Exit

- Highlight Reagent Pack.
- Press Enter.
- Press Move Probe (soft key).
- Open the door.
- Remove the capillary adapter from the front of the probe by pulling it off.
- Replace the adapter with a new one found in the reagent pack. As you put on the adapter, make sure the probe goes into the center hole of the adapter.
- Press Move Probe (soft key) when finished.
- Press Cancel then press Cancel again to return to the Home screen.

☐ Step 2 Remove old cartridge.

- Open the door.
- Remove the old cartridge - lift the cartridge up slightly to clear the lip.
- Mix the new cartridge thoroughly.
- Slide in the new cartridge.
- Close the door.

Replacing the Control Pack Checklist

NOTES:

WARNING: Blood samples and blood products are potential sources of hepatitis and other infectious agents. Handle all blood products and flow path components (waste-line, septum assembly, probe, flow cell, etc.) with care. Gloves and protective clothing are recommended. Dispose of the reagent waste bottle according to your laboratory's biohazardous waste policies.

☐ Step 1 Initiate the procedure

- From the Home (Ready) screen, press Menu.
- Select Change Pack.
- Press enter. A pop-up screen appears.

Change Reagent Pack
Change Control Pack
Exit

- Highlight Control Pack by using the down arrow key.
- Press Enter.

☐ Step 2 Follow the screen directions.

- Open the cover.
- Remove the old cartridge - lift the cartridge up slightly to clear the lip.
- Mix the new cartridge thoroughly.
- Slide in the new cartridge.
- Close the door.

☐ Step 3 Prime the analyzer.

- Press Prime (soft key).

☐ Step 4 Calibrate the analyzer.

- After priming, a pop-up screen appears with a question, "Do you want to recalibrate? Yes or No." Press Yes (soft key).
- Calibration takes place.

☐ Step 5 Validate performance with QC.

- Run QC.
- Document the results.